行政院及所屬各機關出國報告

（出國類別：考察）

九十一年度出國計畫----
赴日考察日本中藥材管理、醫院漢方藥進藥管理及發展新趨勢

服務機關：行政院衛生署中醫藥委員會

出國人　職　　稱：主任委員

　　姓　　名：林宜信

出國地區：日本

出國期間：民國九十一年七月二十八至八月三日

報告日期：民國九十一年九月五日

系統識別號:C09201615

公 務 出 國 報 告 提 要

頁數: 40　含附件: 是

報告名稱:

赴日考察日本中藥材管理、醫院漢方藥進藥管理及發展新趨勢

主辦機關:

行政院衛生署中醫藥委員會

聯絡人／電話:

賴秀麗／02-25872828-267

出國人員:

林宜信　行政院衛生署中醫藥委員會　主任委員室　主任委員

出國類別: 考察

出國地區: 日本

出國期間: 民國 91 年 07 月 28 日 -民國 91 年 08 月 03 日

報告日期: 民國 91 年 09 月 05 日

分類號/目: J0／綜合（醫藥類）　J0／綜合（醫藥類）

關鍵詞:　中藥材、進藥管理

內容摘要: 本計劃之考察目的，主要在了解日本對於中藥材管理、醫院漢方進藥管理及其發展的新趨勢。本次調查除了參觀、訪問各製藥廠以外，並且與東京、大阪兩地的政府機關人員討論將來新藥事法規的施行方向，透過共同開發市場，增進兩國間中藥產業的發展。本項考察期間自民國91年7月28日至91年8月3日止共7天。參與考察人員一行六人，事先請亞太科技協會透過日本東亞技術協會安排爲期七天的考察、討論等活動。期間分別參觀東京都立藥用植物園，救心製藥株式會社，日本漢方生藥製劑協會，厚生勞動省醫政局經濟課，名古屋大學，大阪家庭藥協會，大阪生藥協會，武田藥用植物園以及大阪府健康福祉部藥務課等單位。經由本次考察，有助於進行國際交流外，對於中藥材管理、醫院漢方進藥管理及其發展的新趨勢等已有所掌握，將可作爲我國修訂相關法令及規定之參考。

本文電子檔已上傳至出國報告資訊網

摘要

本計劃之考察目的，主要在了解日本對於中藥材管理、醫院漢方進藥管理及其發展的新趨勢。本次調查除了參觀、訪問各製藥廠以外，並且與東京、大阪兩地的政府機關人員討論將來新藥事法規的施行方向，透過共同開發市場，增進兩國間中藥產業的發展。

本項考察期間自民國 91 年 7 月 28 日至 91 年 8 月 3 日止共 7 天。參與考察人員一行六人，事先請亞太科技協會透過日本東亞技術協會安排為期七天的考察、討論等活動。期間分別參觀東京都立藥用植物園，救心製藥株式會社，日本漢方生藥製劑協會，厚生勞動省醫政局經濟課，名古屋大學，大阪家庭藥協會，大阪生藥協會，武田藥用植物園以及大阪府健康福祉部藥務課等單位。經由本次考察，有助於進行國際交流外，對於中藥材管理、醫院漢方進藥管理及其發展的新趨勢等已有所掌握，將可作為我國修訂相關法令及規定之參考。

目次

壹、目的

本計劃之考察目的，主要在了解日本對於中藥材管理、醫院漢方進藥管理及其發展的新趨勢。本次調查除了參觀、訪問各製藥廠以外，並且與東京、大阪兩地的政府機關人員討論將來新藥事法規的施行方向，透過共同開發市場，增進兩國間中藥產業的發展。此外，還安排了國內相關單位人員至日本相關產業與機構進行實地的見習工作。

貳、過程

本項考察期間自民國 91 年 7 月 28 日至 91 年 8 月 3 日止共 7 天。參與考察人員一行六人（團員名單詳見附錄），事先請亞太科技協會透過日本東亞技術協會安排為期七天的考察、討論等活動。期間分別參觀東京都立藥用植物園，救心製藥株式會社，日本漢方生藥製劑協會，厚生勞動省醫政局經濟課，名古屋大學，大阪家庭藥協會，大阪生藥協會，武田藥用植物園以及大阪府健康福祉部藥務課等單位。

參、心得

(一)、日本由二次大戰結束時，藥品資源匱乏，極力發展本土製藥工業，首先由政府單位建立藥用植物園，主要從事本土中藥的資源確保，經過五十餘年來的演進，藥用植物園仍然保持得相當完整，但是所扮演的功能已經由推廣中草藥栽培而演變成一半以提供學術界共同研究為主，一半為提供附近居民認識藥用植物為目的的藥用植物園，武田製藥廠為日本國產最大的藥廠，年廠值達一兆日元，早期致力餘中草藥研發而有舉世有名的京都武田藥用植物園，經過半世紀的演進，武田藥廠雖然在中藥製劑每年仍有 30 億日元的市場，隨著基因研究的發展，武田的藥用植物園除了接待藥用植物同好外，製藥工業上的功能也只在維持各種植物的基因。

(二)、中藥製劑在 GMP 上的管理是一項相當不容易的事，經過

這次參觀數家中藥廠發現單一製劑工廠容易將GMP的管理提上至cGMP層次，並且與各製藥協會的討論發現各協會能夠提供強大的資訊給會員，會員之間有共同的問題或是漢政府間有必要進行諮詢時，協會都扮演恨重要的角色。並且依照各製藥廠的性質不同有許多的協會可供參加，例如：漢方生藥製劑協會提供所有生廠漢方製劑的廠家參與，而家庭藥協會提供給不論中、西藥的OTC廠家來參與，給藥廠有各種協調的管道。

(三)、名古屋大學的佐藤佑造教授為今年第53回日本東洋醫學會學術總會委員長，特地請教他有關日本在中醫方面的發展情形。關於日本醫院中藥的管理，如果是厚生省指定的210處方中的方劑，藥廠可以比較簡單的得到製造許可（但是近年來由於保險給付以及藥品再評價等等問題，這些處方也不容易取得醫院處方用藥的製造許可）。日本東洋醫學會成立於1950年，當時只有97人，如今已經有9400餘人參加的一個大學會，全國分為八個支部，總部設在東京，學會會員包含經過考試合格的專門醫漢指導專門醫的指導醫師等，各支部每年舉辦2次學會漢各種講習會，總部每年舉辦一次學術大會。今年參加人數2350人。 日本東洋醫學會對發展中醫不遺餘力，其方法先讓有興趣的醫師加入，每年舉辦研討會，發表研究心得，漸漸深入各項問題點，經過多年來的耕耘屬於上乘的中醫學者已經漸漸感覺到中醫的辯証論治的中藥，因此上乘中醫比較喜歡自己調配處方，使用煎劑。這和我國上乘中醫師的理念很接近。

(四)、大阪家庭藥協會及大阪生藥協會針對今後中藥如何客觀的評價交換了意見，例如不定愁訴，痛的定義等等，也都是我國中醫如何客觀定義這些名詞的問題，希望能透過類似這種的交流或學術研討，將這些問題進行統一解釋。另外特別是今年7月26日日本國會剛通過新的藥事法規，針對中藥在日本的製造與銷售將引起巨大的變化，將藥品進口商統一名稱為製造銷售商，使產品的責任寄於銷售商，而製造銷售商可以將產品委託海內外經日本厚生機關認可的藥廠進行生產，這是日本在藥事法

中的一大變革。

(五)、日本針對中藥廠 cGMP 的規定，因有許多過程無法完全依照西藥 cGMP 的準則，因此在中藥廠的 cGMP 也自行研擬一套方案，現在還未完全定案，有鑒於我國中藥廠將全面實施 GMP，同時對於中藥 cGMP 的日本規格也有許多值得參考，已經在此次參訪過程中，聯繫一些值得我國派員前往研習的單位。

肆、建議

(一)、日本各大學藥學部及都道府縣幾乎都設有藥用植物園，雖然功能上已經不是推廣藥用植物栽培，但是在研究和社會教育上仍有十分重要的角色。我國使用中藥比日本更廣泛，基於厚植中藥的基原，生物多樣性保護以及提供中藥基礎研究等目的，國家應該整體規劃高、中、低海拔藥園，同時補助民間設立休閒性藥用植物園，將藥用植物資源與民間教育結合，厚植中藥來源。

(二)、有關日本中藥 GMP 與 cGMP 的探討，已經在此次參訪過程中徵求中醫藥委員會林主委同意，將派遣中醫藥委員會相關人員來日本進行一個月的研修活動，並且已經徵求日本 JPS 藥廠，救心製藥株式社，大幸藥品株式會設以及大阪府廳等單位給於研修的機會。

(三)、日本東洋醫學會成立五十年來，已經形成頗具規模的學術團體，我國也有類似的醫學團體，希望能夠加以整合，使中醫藥學術力量表現在學會上，如此容易進行國際學術交流，例如明年 11 月將在我國舉行國際東洋醫學會，國內如有類似於日本東洋醫學會則可以直接對應於國際東洋醫學會的組織，方便國際交流，也容易吸引日本今後在新藥事法規上的進口商來台採購中藥。

(四)、中醫、中藥的科學研究在我國也有許多優於日本的地方，例如舌診的數位化研究，切脈的數位化研究，這些都是和針灸一樣值得和國際建立交流的題目，希望國內

增加和國際交流的機會，如同前項。期望國際上中醫藥的科學化發展不再是以美國思想為主導。

附　　錄

赴日本考察日本中藥材管理、醫院漢方藥進藥管理及發展新趨勢

附　錄

日本中藥材管理、醫院漢方藥進藥管理及發展新趨勢（02-07-06）考察團名單

考察期間：自 2002 年 7 月 28 日至 2002 年 8 月 3 日

團員職稱	姓名	出生年月日	服務機關（現所屬）	現職（役職）	專長（專攻）	語言能力		備註
						日	英	
團長	林宜信 Lin I-Hsin	48.04.23	行政院衛生署中醫藥委員會	主任委員	新藥臨床試驗、臨床醫學、免疫學、腫瘤學	可	佳	T：02-25994326 F：02-25994327
總幹事	沈重光 Shen Chung-Guang	32.03.02	順天堂藥廠股份有限公司	總經理	中西藥理學、中藥製技、行銷業務、行政管理	佳	佳	T：02-23957070 F：02-23213707
翻譯	黃麗修 Huang Li-Hsiu	48.01.01	台中技術學院	副教授	日本文學、英國文學	優	優	T：04-22232679 F：04-22203999
團員	吳金濱 Wu Chin-Pin jbwu@mail.cmc.edu.tw	41.09.30	中國醫藥學院	教授	藥學、生藥學、中草藥生物科技	佳	可	T：0953025188 F：04-22057092

團員職稱	姓名	出生年月日	服務機關（現所屬）	現職（役職）	專長（專攻）	語言能力		備註
						日	英	
團員	郭槐秋 Kuo Huan-Chiu	34.01.05	統一科技股份有限公司	總經理	醫藥	佳	佳	T：02-26582136 轉 101 0910013618 F：
團員	范育仁 Fan Yu-Jen	39.12.15	高平貿易股份有限公司	總經理	藥學	佳	可	T：02-25051611 0918078829 F：02-25160695

Outline of
Pharmaceutical Administration in Osaka Prefecture

The edition of 2002

Pharmaceutical Affairs Division
Dept. of Public Health and Welfare, Osaka Prefectural Government

CONTENTS

Outline of
Pharmaceutical Administration in Osaka Prefecture

Dept. of Public Health and Welfare,
Osaka Prefectural Government

1. Introduction

Pharmaceutical administration in Osaka Prefecture includes the following 8 laws:

- Pharmacist Law
- Pharmaceutical Affairs Laws
- Poisonous and Deleterious substances Control Law
- Narcotics and Psychotropics Control Law
- the Cannabis Control Law
- the Opium Control Law
- the Stimulant Control Law
- Bleeding and Blood Donor Supply Services Control Act

The above-mentioned 8 laws are established by the central government and its jurisdiction extends to the whole country. The interpretation, operation and instruction of these 8 laws are to be controlled by the Pharmaceutical and Medical Safety Bureau and the Health Policy of the Ministry of Health, Labour and Welfare.

Japan has 3311 local governments (47 Prefectures, 23 Tokyo special sections, 12 government-ordinance-designated cities, 671 cities, 1991 towns and 567 villages as of July 1, 2000), and Osaka is one of the 47 prefectures. Each of the 47 prefectures includes Pharmaceutical administration supervision division which, in Osaka, is the Pharmaceutical Affairs Division of the Department of Public Health and Welfare.

The minister for Health and Welfare of Prefectural Governor has authorization for the regulation of the laws. The authority to grant the distribution license of establishment of the health center for part of the drug products and for the poisonous and deleterious substances was transferred to the ordinance-designated cities in April 1997 and 2000, respectively.

Jurisdiction over the above authorities, taking Pharmaceutical Affairs Law for example, assignments are as follows;

Table 1

	Production (import) of Drugs	Sales of Drugs
Approval & permits by	**Ministry of Health, Labour & Welfare** -Biological preparation -National assay products -Gene recombination applied products -Radiopharmaceuticals **Prefectural Governor** -Other Pharmaceuticals	Prefectural Governor ※Mayors of ordinance-designated cities
Site inspection done by	**Ministry of Health, Labour & Welfare** **Prefectural Governor**	Ministry of Health, Labour & Welfare Prefectural Governor ※Mayors of ordinance-designated cities
Revocation of the approval suspection of Business	**Ministry of Health, Labour & Welfare** Prefectural Governor	Prefectural Governor ※Mayors of ordinance-designated cities

※ The business status is classified into first-class sellers and special sellers.
Ordinance-designated cities in Osaka Prefecture ;
Osaka-city, Sakai-city, Higashi Osaka-city.

If there is any opinion discrepancy between the central government and any prefectural government or between prefectural governments, the central government will make the decision on the interpretation of the legislation. The application of the legislation is discussed and decided by the central government and the prefectural government.

2. Organizations of the Osaka Prefecture

(1) Organization Chart of Osaka Prefectural Government.....(→**Reference** 1)

(2) Organization Chart of Department of Public Health and Welfare.....(→**Reference** 2)

(3) Organization Chart of Pharmaceutical Affairs Division.....(→**Reference** 3)

3. Pharmaceutical Administration in Osaka Prefecture

(1) As already mentioned in 1., pharmaceutical administration in Osaka prefecture is controlled by Pharmaceutical Affairs Div. Some of the services are performed by the Osaka prefectural wide area (4) health center and ordinance-designated cities as described next page:

	Pharmaceutical Administration	
44 municipalities in Osaka Prefecture	Osaka City	-Direct Control of Pharmaceutical Affairs Division -The authorities to grant the general distribution license and special distribution license for pharmaceutical products as well as the poisonous and deleterious substances distribution license have been transferred to each municipal government.
	Sakai City	
	Higashi-Osaka City	
	Remaining 41 municipalities	-Prefectural wide area Health Centers (4 Centers) -Carry out duties regarding pharmaceutical affairs within their own jurisdictions. (ex.)Application flow, on-the-spot inspection and instruction (not authorized for approval & administrative measures.)

(2) Pharmaceutical Industry of Osaka Prefecture (→**Reference** 4)

(*Business category of First- or Third-Class Sellers of Drugs and Poisonous and Deleterious Substances Sellers for which the administrative right was transferred to the ordinance-designated city account for facilities licensed by the Governor, Osaka Prefecture.)

(3) Sharing of the Operations among the Groups of the Pharmaceutical Affairs Division (→**Reference** 5)

① Pharmaceutical Distribution Group

a) Inspection Items for On-the-spot Inspection of Pharmacies.....(→**Reference** 6)

b) Flow-chart of Guidance Procedures in case of Violation.....(→**Reference** 7)

c) Flow of the Application for the License for the Pharmacy, etc.....(→**Reference** 8)

d) Review criteria and guidance for Drug Wholesalers.....(→**Reference** 9)

e) Self inspection items of Drug Wholesalers.....(→**Reference** 10)

② Pharmaceutical Production Group

a) Flow-chart of Guidance Procedures in case of Violation.....(→**Reference** 7)

b) Guidance on GMP.....(→**Reference** 11)

c) Flow of the Application for Approval, etc.....(→**Reference** 12)

d) Drugs, etc. to be Approved by Prefectural Governments.....(→**Reference** 13)

③ Medical Devices Group

a) Flow-chart of Guidance Procedures in case of Violation.....(→**Reference** 7)

b) Flow of the Application for Approval, etc.....(→**Reference** 12)

c) Drugs, etc. to be Approved by Prefectural Governments.....(→**Reference** 13)

④ Narcotics and Poisonous and Deleterious Substances Group

a) Flow-chart of Guidance Procedures in case of Violation.....(→**Reference** 7)

b) " No Drug Abuse" 5-year Project in Osaka Prefecture, (Drug Abuse Eradication Campaign).....(→**Reference** 14)

⑤ General Planning Group

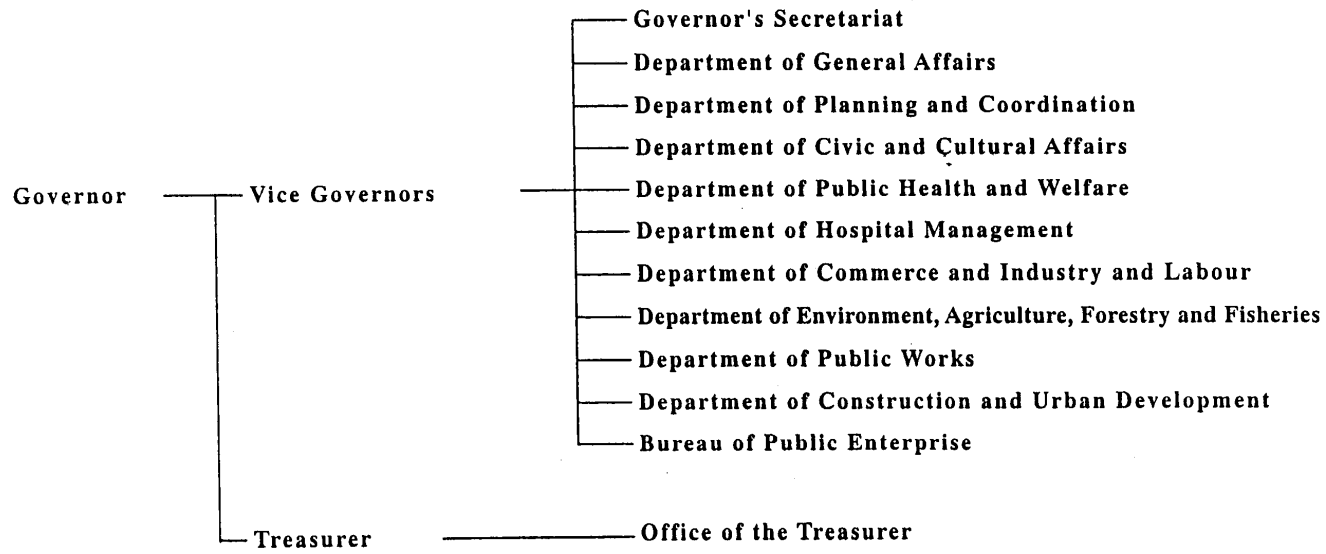
a) The Information Exchange System for Drug Safety .....(→**Reference** 15)

b) Blood Donation Promotion Organization of Osaka Prefecture.....(→**Reference** 16)

(Reference 1)

Organization Chart of Osaka Prefectural Government

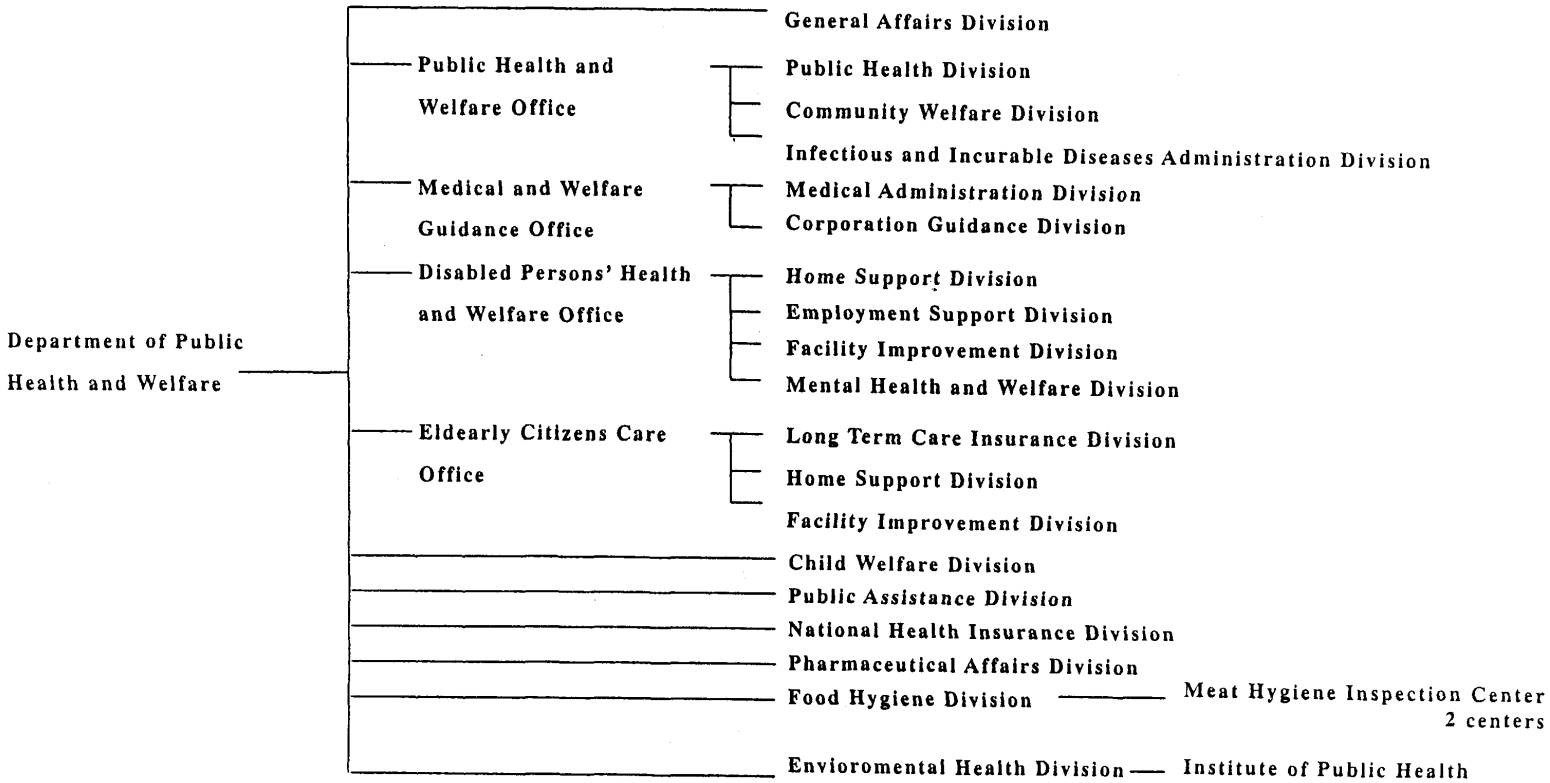
(As of April 1, 2002)



(Reference 2)

Organization Chart of Department of Public Health and Welfare

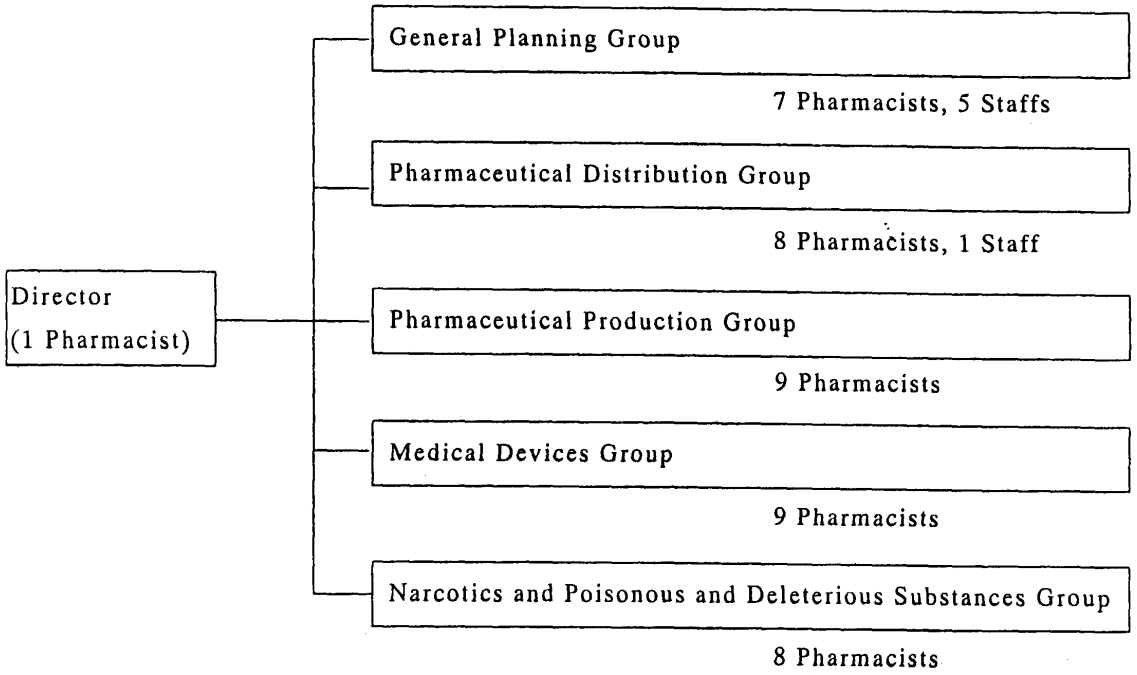
(As of April 1, 2002)



(Reference 3)

ORGANIZATION CHART OF PHARMACEUTICAL AFFAIRS DIVISION

(As of April 16, 2002)



Amount Number of Staffs: 48

Pharmacists: 42

Staff: 6

(Reference 4)

Pharmaceutical Industry of Osaka Prefecture (As of March 31, 2002)

Manufacturers	Number
Pharmaceutical	
*Professional	
The Minister	8
The Governor of Osaka Prefecture	233
Pharmacies	1,621
Quasi-drugs	
The Governor of Osaka Prefecture	182
Cosmetics	
The Governor of Osaka Prefecture	269
Medical Devices	
The Governor of Osaka Prefecture	250
Importers	
Pharmaceutical	
The Minister	3
The Governor of Osaka Prefecture	120
Quasi-drugs	
The Governor of Osaka Prefecture	29
Cosmetics	
The Governor of Osaka Prefecture	212
Medical Devices	
The Governor of Osaka Prefecture	166
Repairer specializing in medical device	335
Pharmacies	3,147

Drug Sellers	Number
First-Class Sellers*1	
Wholesalers*2	1,157
Retailers	476
Yakushu-sho	1,128
(Second-Class Sellers)*3	
Special Sellers*4	110
(Third-Class Sellers)	
Household Distribution Seller*5	536
Medical Device Seller	26,589
Medical Device Lessor	353
Narcotics	
Whole Sellers	25
Retailers	1,555
Managers	609
Users	11,087
Researchers	139
Psychotropics	
Whole Sellers	4
Establishers of Psychotropics -	
Experimental research facilities	116
Stimulants	
Manufacturers	1
Using Institutions	12
Researchers	72
Retail dealer of Bulk Preparations	
such as specified Narcotics	328

Raw Material of Stimulants	Number
Manufacturers	4
Importers	1
Exporters	6
Users	119
Researchers	57
Hemp Researchers	27
Poisonous and Deleterious Substances	
Manufactures	
The Minister	63
The Governor of Osaka Prefecture	266
Importers	
The Minister	195
The Governor of Osaka Prefecture	46
Sellers	
Ordinary Sellers	2,060
Agricultural Substances	273
Designated Substances	33
Occupational Users	
Plate Industry	250
Thermal Retreatment Industry	7
Transporter	79
Termite Exterminator	1
Blood	
Blood Collector	13

*1 First-Class sellers are those which can sell drugs.
*2 First-class wholesalers are those which are not permitted to sell drugs directly to general consumers.
*3 Second-class sellers are those which can sell drugs other than those designated by the Minister.
*4 Special (third-class) sellers are those which sell drugs specified by the prefectural governors.
*5 Household Distribution Sellers are those which can sell drugs by household distribution as specified by the prefectural governors based on standard specified the Minister.

(Reference 5)

Sharing of the Operations among the Groups of the Pharmaceutical Affairs Division

Name of section	Contents of job
General Planning Group	1. Promotion of the pharmaceutical industry. 2. Promotion of blood donation. 3. Licenses and others provided for in the Bleeding and Blood Supply Service Control Law. 4. Registration of poisonous and deleterious substances sellers. 5. Matters relating to the Examination for persons in charge of "poisonous or deleterious substances" and the "Examination for second- class drug sellers". 6. Matters relating to councils such as Pharmaceuticals Affairs Council. 7. Matters relating to Rational use of drugs. 8. Matters relating to administrative investigations. 9. Services relevant to the Good Post Marketing Surveillance Practice (GPMSP).
Pharmaceutical Distribution Group	1. On-site inspection of the facilities of the pharmacists and distributors to which the Pharmaceutical Affairs Law and the Pharmacists Law are applied. 2. Disposition of violators concerning facilities referred in 1. 3. Disposition of adulterated drugs, etc. Concerning facilities referred in 1. 4. Licenses for establishing pharmacies. 5. Licenses for drug sellers. 6. Notification by medical device sellers. 7. Matters relating to the GMP inspection for approvals/licenses. 8. Guidance of pharmaceutical inspectors. 9. Concerning the promotion of separation of dispensing from medical practice.
Pharmaceutical Production Group	1. On-site inspection of the facilities of the pharmaceutical manufacturers and importers/distributors to which the Pharmaceutical Affairs Law is applied 2. Disposition of violators concerning facilities referred in 1. 3. Disposition of adulterated drugs, etc. Concerning facilities referred in 1. 4. Operations related to the manufacturing and importing approval for pharmaceutical products 5. Concerning the promotion of separation of dispensing from medical practice. 6. Inspection to issues the GMP certificates. 7. Matters relating to the "Assay" of drugs 8. Taking-out and examinations of drugs. 9. Services relevant to extravagant advertisements of drugs. 10. Re-evaluation of drugs 11.Re-examination of drugs. 12. Concerning guidelines and inspection of so-called health foods. 13. Services relevant to international exchange of technologies.
Medical Devices Group	1. On-site inspection of the facilities of the manufacturers and importers/distributors of medical devices, quasi-drugs and cosmetic products to which the Pharmaceutical Affairs Law is applied 2. Disposition of violators concerning facilities referred in 1. 3. Disposition of adulterated medical devices, adulterated quasi-drugs and adulterated cosmetic products. Concerning facilities referred in 1 4. Operations related to the manufacturing and importing approval for medical devices, quasi-drugs and cosmetic products 5. Matters relating to the GMP inspection for approvals/licenses. 6. Inspection to issues the GMP certificates. 7. Operations related to the acceptance/shipment inspection of medical devices, quasi-drugs and cosmetic products 8. Control of the exaggerated advertisement of medical devices, quasi-drugs and cosmetic products
Narcotics and Poisonous and Deleterious Substances Group	1. On-site inspection of the facilities of the manufacturers and importers/distributors to which the Poisonous and Deleterious Substances Control Law, the Narcotics and Psychotropic Control Law, the Stimulant Control Law, the Opium Control Law and the Cannabis Control Law are applied 2. Disposition of violators concerning facilities referred in 1. 3. Operations related to the accidents or other incidents which occur in the facilities specified in 1 above 4. Matters relating to registration to manufacture/import poisonous and deleterious substances. 5. Licenses and others provided for in Narcotics and Psychotropics Control Law Stimulant Control Law, Opium Control Law and Cannabis Control Law. 6. Prevention of drugs abuse such as stimulants, etc.

INSPECTION ITEMS FOR ON-THE-SPOT INSPECTION OF PHARMACIES

(Reference 6)

Part	Check Item	Yes/No
(Ⅰ)Supervisor Pharmacist	(1) Is the supervisor pharmacist dedicated to the operation of the pharmacy only and free from other pharmaceutical-related business?	
	(2) Does a supervisor pharmacist always present at the pharmacy?	
	(3) Is the supervisor pharmacist responsible for the dispensing, formulation, sales, delivering and granting of pharmaceutical products, and other related matters?	
	(4) Does the supervisor pharmacist retain records of the analysis, disposition of defective products or other operations related to pharmacy administration?	
(Ⅱ)Design of the Pharmacy Building and Facilities	(1) Is a license of operation displayed at near the entrance or a place easy to be noticed?	
	(2) Does the place where the drugs are displayed or given have the brightness of 60 luxes or more?	
	(3) Is the pharmacy well ventilated and clean?	
	(4) Is the pharmacy clean?	
	(5) Does the pharmacy have a cold and dark storage facility, which can be locked up?	
	(6) Is the pharmacy clearly separated from the residence or a dirty place?	
	(7) Does the pharmacy cover the area of 19.8m^2 or more?	
(Ⅲ)Dispensing Room	(1) Does the dispensing room have the floor space of 6.6 m^2 or more?	
	(2) Are the ceiling and the floor of the dispensing room boarded or concrete?	
	(3) Does the dispensing room have the brightness of 120 luxes or more?	
	(4) Is the dispensing room properly ventilated?	
	(5) Is the dispensing room clean?	
	(6) Is the pharmacy furnished with the equipment and books necessary for dispensing and analysis?	
	(7) Are any of the drugs used for dispensing not deteriorated, decomposed or defective?	

(Ⅰ) Supervisor Pharmacist

(Ⅱ) Design of the Pharmacy Building and Facilities

(Ⅲ) Dispensing Room

(IV) Consideration by the owner	(1) Does the owner consider well so that the supervisor pharmacist of the pharmacy can perform the service well?	
	(2) Have the notifications of replacement of the supervisor pharmacist been submitted without delay?	
	(3) Does the pharmacy always keep its supervisor pharmacist attended to its shop while it is opened?	
(V)Drugs	(1) Is any of the defective drugs not stored, displayed, sold or granted?	
	(2) Are any drugs with foul labeling not storing, displaying, selling or granting?	
	(3) Are the drugs required to be stored in cold and dark stored accordingly?	
	(4) Do they keep no falsified or exaggerated advertisement of drugs?	
	(5) Are designated drugs properly handled?	
	(6) Do they pay enough attention to the drugs' with usage/ validity period?	
	(7) Are records retained in granting/acceptance of the drug products with the code indicating the recording obligation on its package?	
	(8) Are any of the drugs used for dispensing purpose not sold directly to the general consumers?	
	(9) Are drugs stored and displayed separately from the other products?	
	(10) Are drugs displayed inside the pharmacy? (They should not be outside.)	
(VI)Poisonous and Powerful Drugs	(1) Are poisonous and powerful drugs indicated properly?	
	(2) Is poisonous and powerful drugs displayed and stored separately from other drugs?	
	(3) Is the storage of poisonous drugs locked up?	
	(4) Is the Granting/Acceptance Document completed and signed by the recipient in selling/granting the poisonous or powerful drugs to the general consumers?	
	(5) Is the necessary confirmation made before selling or granting poisonous and powerful drugs to doctors or pharmacists?	
	(6) Are records for granting of poisonous and powerful drugs stored for 2 years?	
	(7) Are poisonous and powerful drugs not sold to the persons under 14 years old, etc.?	

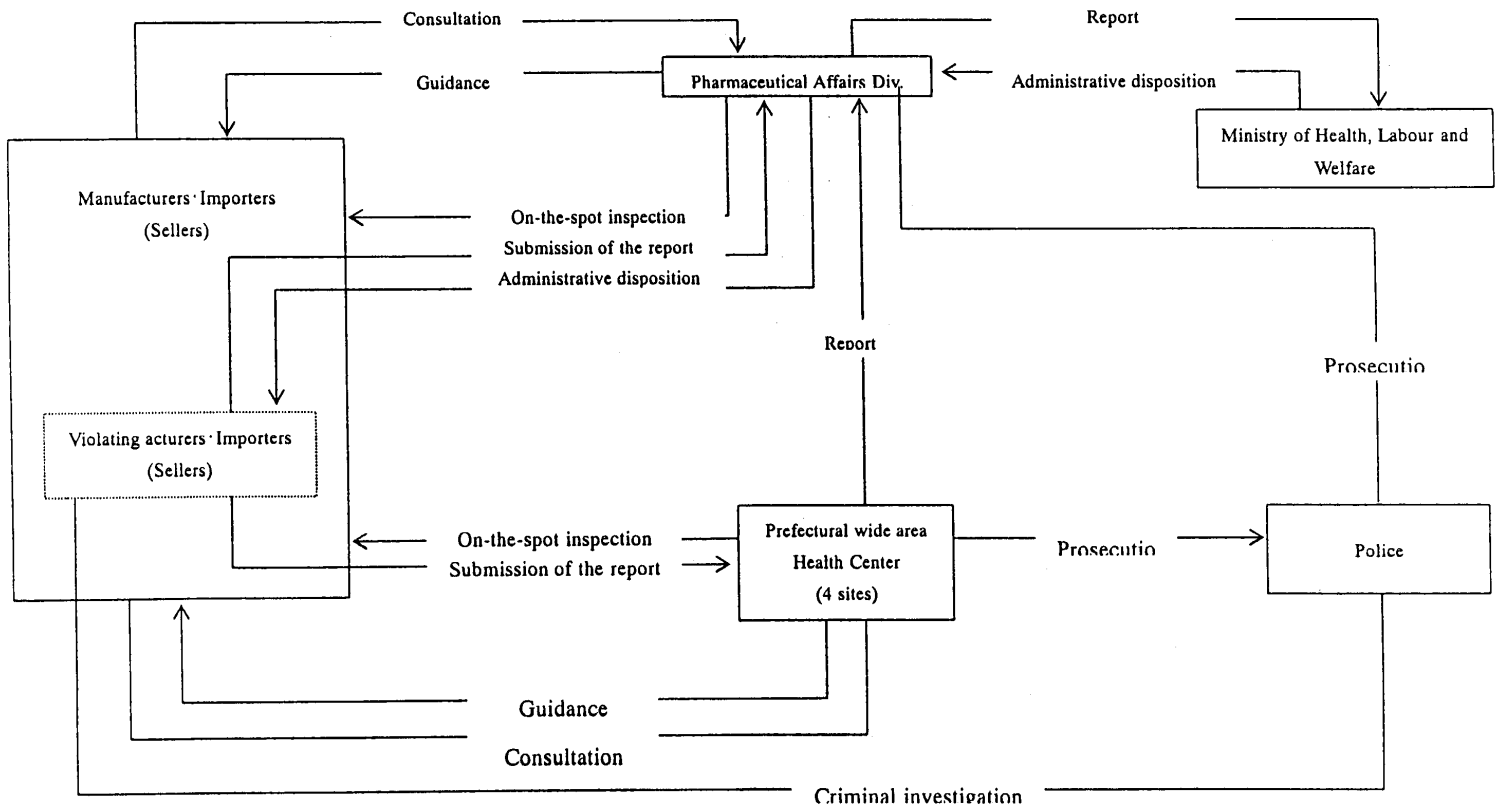
(IV) Consideration by the owner
(V) Drugs
(VI) Poisonous and powerful drugs

(Ⅶ)Dispensing and Formulation	(1) Are drugs dispensed in accordance with the prescription by doctor?	
	(2) Are dispensing recorded?	
	(3) Is the entry made in the prescription as specified by the laws and regulations in dispensing drugs?	
	(4) Are prescriptions stored for 3 years?	
	(5) Does the pharmacy have a license of dispensing?	
	(6) Does the supervisor pharmacist control the dispensing in the pharmacy?	
(Ⅷ) Information Provision etc.	(1) Does the pharmacy make efforts to provide purchasers (users) of drugs with information required for their proper use ?	
	(2) Does the pharmacy provide patients with information necessary for the proper use of the drugs dispensed in the pharmacy?	
(Ⅸ)Miscellaneous	(1) Has the effective period of approval not expired?	
	(2) Is the *health food* handled appropriately?	
	(3) Does each of the pharmacists at the pharmacy carry a proper name plate or an armband?	
	(4) Are complaints handled appropriately?	
(Ⅹ)Poisonous and Deleterious Substances	(1) Has registration not expired?	
	(2) Are granting records or account books filled in appropriately?	
	(3) Are poisonous /deleterious substances not sold to the youths under 18 years of age or to people who seems to have problems in handling them?	
	(4) Is the storage facility prepared so that poisonous and deleterious substances can be stored separately from other drugs?	
	(5) Can the storage be locked up?	
	(6) Does the storage and displays for poisonous and deleterious substances have an indication as regulated?	
(Ⅺ)Psychotropic Medicines	(1) Are psychotropic medicines granted to people who is related to patients, after prepared in accordance with the prescription by doctors?	
	(2) Are psychotropic medicines stored and controlled properly in the facility, which is equipped with a lock?	
	(3) Is appropriate labeling displayed on the container or wrapping? e.g.) the first Chinese character of "psychotropic medicines" in a circle.	
	(4) Is disposal of psychotropic medicine carried out properly? Is the record of disposal stored for 2 years?	
	(5) Is the notification of adverse events related to psychotropic drugs immediately submitted?	

(Ⅶ) Dispensing and Formulation
(Ⅷ) Information Provision etc
(Ⅸ) Miscellaneous
(Ⅹ) Poisonous and Deleterious Substances
(Ⅺ)Psychotropic Medicines

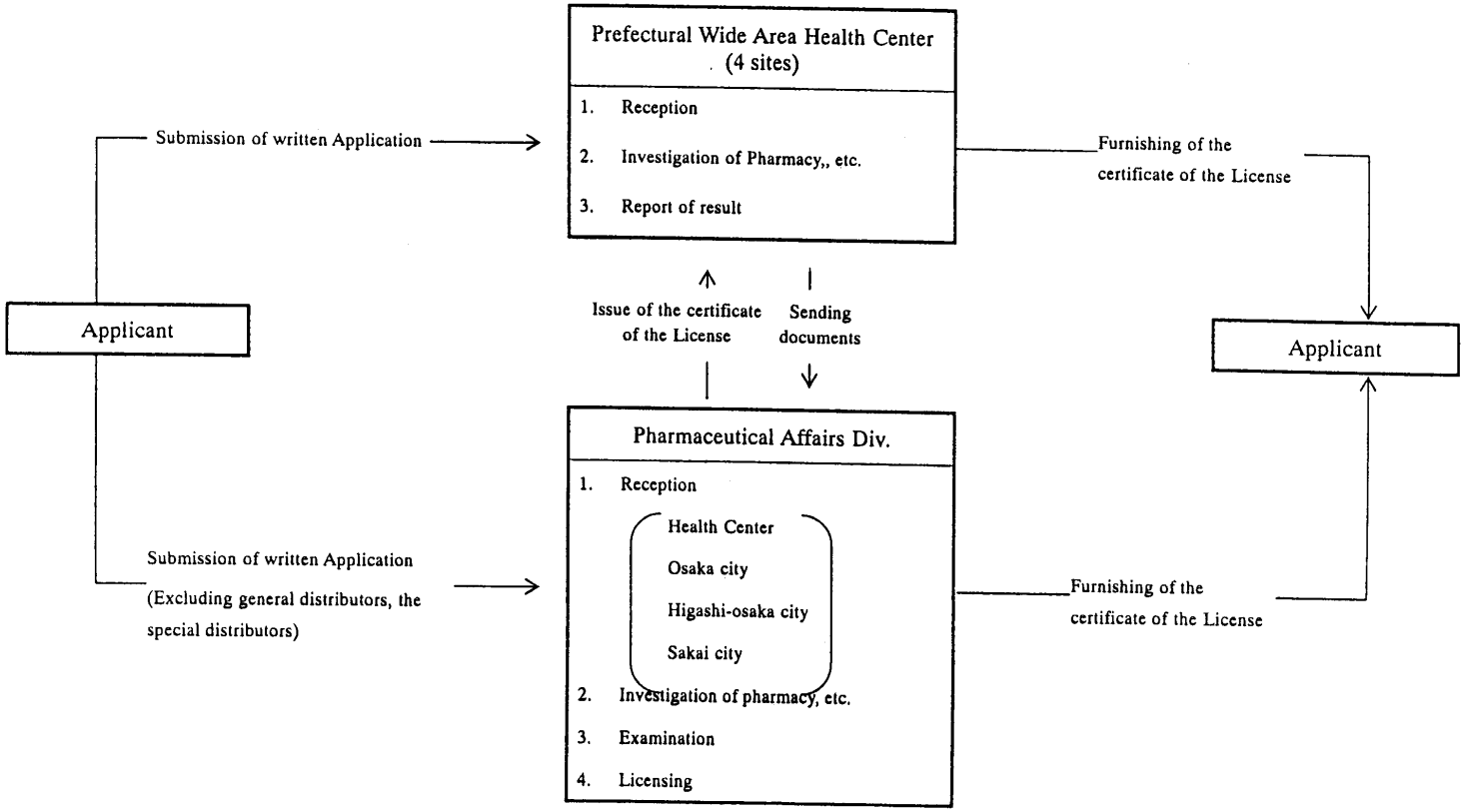
(Reference 7)

Flow-chart of Guidance Procedures in case of Violation



(Reference 8)

Flow of the Application for the License for the Pharmacy, etc



(Reference 9)

Review criteria and guidance for drug wholesalers: Drug Wholesalers are granted to sell drugs only to the proprietors of community pharmacy, drug manufacturers or sellers, or corporate business of hospitals, clinics, or veterinary hospitals.

Legal basis	Article/ Provision		Statutory provision	Review criteria	Guidance
Law	6	1	First-Class Sellers of which buildings and facilities are not in conformity to the standards provided by the ministerial ordinance may not be granted a license.	Business premises of Drug Wholesalers collectively mean storage facility [warehouse (including subdivided storerooms)] and office room (equipment) in combination, and their buildings and facilities should meat the following items.	
Law	2 6	3	Drug Wholesalers with license must not operate its business at the licensed premises to sell or confer drugs to persons other than the proprietors of pharmacy, drug manufacturers, importers, or sellers, and corporate businesses of hospitals, clinics, or veterinary hospitals, unless otherwise granted by the prefectural governor.		
	2		I. Buildings and facilities	Name plate for the licensed premises should be displayed at an easily visible place.	
	- 2		Buildings and facilities of the business premises are standardized as follows: (1) The premises should be fully ventilated and clean. (2) The premises should be definitely separated from the living area and unclean areas. (3) Drug products should always be exhibited in the premises, which are luminous at 60 lux or brighter at the site where drugs are dispensed. (4) The premises should be installed with a light-resistant refrigerator, except when drugs to be refrigerated are not dealt with. (5) The premises should be installed with a lockable storage facility.	1. Buildings and facilities of the warehouses (1) The flooring and walls should be of woods or concrete, or made of quasi materials. (2) Facilities to prevent from the direct sunlight should be equipped. (3) The electric or gas refrigerator (including refrigerators with a light-shielding glass) should be provided as a light-resistant refrigerator. (4) The lockable storage facility should be robust and hardly movable. (5) A facility to appropriately control temperature and humidity should be provided. (6) The warehouse should be definitely separated from the office room or others by the partition walls standing from the floor to the ceiling, with the entrance being provided with the door (to be locked as needed). When the Fire Defense Law does not allow a barrier extending from the floor to the ceiling, a minimal opening is permissible, unless it is of concern from viewpoints of health care and hygiene.	The tatami mats and carpets are not allowed(except for dustproof or mothproof-finished carpets). Facilities to prevent insects, dusts, and rodents should be provided. A thermograph should be provided, for drugs to be strictly controlled with temperature.
			The premises should be installed with a facility of about 100 m^2 or more to store drugs sanitarily and safely, except when drugs can be stored sanitarily and safely, and the required area is inevitably not met.	(7) Floor area should be over 100 m^2. *Calculation of area: Inside area as an operative area *Combined area of the major warehouse and subdivided storerooms to be over 100 m^2. This is not applied to exceptional wholesalers (Small-Size Wholesalers and Wholesalers for Special Items or Sample Items) (Refer to 2. Buildings and facilities for the exceptional warehouses).	

Legal basis	Article/ Provision		Statutory provision	Review criteria	Guidance
				•The subdivided storerooms (storage facility of drugs located at other than the business premises) should meet the followings. a. To meet the standards for buildings and facilities of warehouses. b. Area of the major business premises excluding the subdivided storerooms to be over 13.2 m^2. (Notification No. 552 of the PAB/MHW, dated June 16, 1981). c. The subdivided storerooms to be located in Osaka Prefecture. d. Commission of drug control duties to warehousers is not allowed. 2. Buildings and facilities for the exceptional warehouses Area less than 100 m^2 is permissible, if the warehouses of wholesalers meet the following items. In this case, area of the business premises should be over 13.2 m^2, excluding the subdivided storerooms. The warehouse area is 3.3 m^2 or over, in conformity to a provision for buildings and facilities in above 1.	
					Buildings and facilities of office room (1) To be definitely separated from the living area or unclean areas. (2) The office is roomy enough for office works.
				(1) Less drugs are being handled (Small-Size Wholesalers). (2) Only drugs cited below are handled (Wholesalers for Special Items). a. Drugs only for manufacturing. b. Sodium bicarbonate as a raw material of chemical drugs, etc. and drugs such as glucose and lactose. c. Sanitary materials such as gauze and absorbent cotton as drugs. d. Biological drugs such as vaccines and blood products. e. Other drugs specified by business category (diagnostic reagents such as test agents, public hygiene drugs for epidemic prevention, and dental/oral drugs). (3) To serve only samples at branch offices of drug manufacturers (importers) (wholesaler for sample items). • Samples: preparation examples, investigational drugs, and free or trade samples of non-prescription drugs.	
Law			II. Personal requirements License for First-Class Sellers is not granted, if any one of the followings is met.		

Legal basis	Article/ Provision		Statutory provision	Review criteria	Guidance
Corresponding application	6	2	Applicant (including executives, if the applicant is corporate) meets any one of the following conditions. a. It is not three years since the license was revoked according to Provision 2, Article 75 of the law. b. It is not three years since imprisonment or further punishment was sentenced, executed, and no longer executed. c. It is not two years since the Pharmaceutical Affairs Law, the Narcotics and Psychotropics Control Law (Law No. 14, 1953), the Poisonous and Deleterious Substances Control Law (Law No. 303, 1950), other laws relating to the Pharmaceutical Affairs Law or legal punishment based on infringement of these laws was violated, excluding the applicants meeting above a. and b. d. Adult wards, mental defectives, and addicts of narcotics, cannabis, opium, or stimulants. e. Persons who apparently discourage pharmacists to fulfill their duties to control the business premises of the First-Class Sellers according to the Pharmacists Law, because of inclinations and loose morals.	Scope of additional posts of the supervisor (Notification No. 1177 of the PAB/MHW, dated December 28, 1995) (1) The supervisor can concurrently supervise the business premises for multiple Drug Wholesalers at the shipping center which the Drug Wholesalers jointly operate.	
Law	27		Pharmacist(s) should be assigned to actually supervises the business premises of the Drug Wholesalers.	(Notification No. 462 of the PAB/MHW, dated March 31, 1992)	
Corresponding application	8			(2) The supervisor for a Drug Wholesaler handling only the in vitro diagnostics or samples at branch office of a manufacturer (importer) can concurrently supervise the business premises of Drug Wholesalers (across the country) handling other in vitro diagnostics or samples of the same manufacturer (importer).	A representative to concurrently supervise the business premises is established, and a bylaw "Provision for business management of supervisors with additional post" should be provided.
			Permission for the supervisor to have additional posts The supervisor of First-Class Sellers should not be engaged in supervision or related pharmaceutical affairs at other business premises as a business, unless otherwise permitted by the Governor of the First-Class Seller's residence.	(3) The supervisor can also supervise business premises of the same Drug Wholesaler located in Osaka Prefecture, when either 1 or 2 of the following conditions is met. 1. a. No tally trade is served. b. Not licensed for change in recipients to whom drugs are delivered. c. Not serving narcotics, stimulants and psychotropics. 2. a. When exposition of 7 days or less is to be held. b. At the exposition, a and b of above 1 are met. c. Not serving narcotics, stimulants and psychotropics.	
Law Number	26 2	3 1	Permission for Drug Wholesalers to sell to other than pharmacies The number of pharmacists who can actually engage in pharmaceutical affairs at business premises of First-Class Sellers, provided by the MHW Ordinance based on the Article 6, Provision 1, Item 1-2 in corresponding application of Article 26, Provisions 2 and 4 of the law is one.	•License for change in recipients to whom drugs are delivered The change is not permitted, except for a range of recipients to whom drugs are delivered and drug items to sell (shown in a separate Table 1).	
Law	2 4	2	Renewal of license License for Drug Sellers becomes invalid when the term expires, unless the license is renewed every 6 years.	The standards for licensing should be secured according to Article 26, Provision 2 of the law [corresponding application of Article 6 of the law (excluding Provision 1 of the Article 6)]	

(Reference 10)

Self inspection items of Drug Wholesalers

Supervising pharmacist:	(1) Whether or not the supervising pharmacist is engaged in other duties relating to pharmaceutical affairs. (2) Whether or not the supervising pharmacist always works at the business premises. (3) Whether or not the supervising pharmacist provides records on supervision of the First-Class Sellers in relation to selling, conferring and handling of drugs or others. (4) Whether or not the supervising pharmacist supervises employee not to cause problems with health care and hygiene, paying attentions necessary to control buildings, facilities, and drugs and to fulfill other duties.
Business premises:	(1) Whether or not license is displayed over the counter or at any other easily viewable place in the office. (2) Whether or not the premises are fully ventilated and clean. (3) Whether or not any light-resistant refrigerator is installed, in the cases of handling drugs to be kept refrigerated. In addition, whether or not a lockable storage facility is provided. (4) Whether or not the business premises are definitely separated from the living area or unclean areas. (5) Whether or not the business premises are provided with an appropriate facility of 100 m2 or over to store drugs sanitarily and safely. Or for Small-Size Wholesalers, whether or not area of the business premises is 13.2 m2 or over.
Proprietor's solicitude:	(1) Whether or not the proprietor of wholesalers is sufficiently thoughtful, so that the supervising pharmacist can fulfill duties. (2) Whether or not replacement of the supervising pharmacist is notified without delay, according to Article 10 of the law (correspondingly applied by Article 38).
Drugs	(1) Whether or not adulterated drugs are stored, displayed, sold or conferred. (2) Whether or not false-labelled drugs are stored, displayed, sold or conferred. (3) Whether or not drugs to be kept refrigerated and shielded from the light are retained, accordingly. (4) Whether or not drugs are advertised with false or exaggeration. (5) Whether or not shelf-life or expiration date of drugs is fully paid attention. (6) Whether or not records of release/acceptance of drugs with the code indicating the recording obligation on its package are provided. (7) Whether or not the returned or recalled products are stored, in distinction from other drugs, with proper display. (8) Whether or not drugs are stored or displayed in distinction from other products.
Poisonous and powerful drugs:	(1) Whether or not poisonous or powerful drugs are properly displayed. (2) Whether or not poisonous drugs are stored in a lockable storage facility in distinction from others. (3) Whether or not powerful drugs are stored or displayed in distinction from others. (4) Whether or not poisonous or powerful drugs are sold or conferred to Drug Sellers or doctors, upon confirmation of their official license. (5) Whether or not a transfer certificate of poisonous or powerful drugs to recipients licensed for change in recipients to whom drugs are delivered is retained for 2 years.
Others:	(1) Whether or not drugs are delivered to legitimate recipients in conformity to the Pharmaceutical Affairs Law. (2) Whether or not information is appropriately collected and delivered. (3) Whether or not actions are appropriately taken for reevaluation results. (4) Whether or not complaints from customers are appropriately dealt with. (5) Timing of license renewal is to be confirmed (expiration date).

1) Self inspection is conducted according to Notification No. 406 of Director-General, PAB/MHW, May 28, 1983.
2) Self inspection is regularly conducted according to the plan, and necessary measures are to be taken based on the inspection results.

(Reference 11)

Guidance on GMP

by Pharmaceutical Affairs Division of the Department of Public Health of Osaka Prefecture

1. Introduction

As pharmaceutical products are used for diagnosis, treatment and prevention of disease, they play an important role in citizens' health and hygiene. In order to ensure their effectiveness, safety and quality they are subjected to various regulations, in accordance with the Pharmaceutical Affairs Law, throughout the process from manufacture through to sales.

As progress is made in medical and pharmaceutical science, society has demanded the provision of pharmaceuticals with a higher degree of quality assurance. In order to fulfill these demands, the need arose to establish a system by which the entire manufacturing process of pharmaceutical products, from intake of raw materials to distribution of the finished product, could be fully regulated. In October 1979, taking the opportunity provided by the revision of the Pharmaceutical Affairs Law, the GMP was legislated.

Matters that had been implemented under the guidance of the current Administration, were then formally stipulated in the "Regulations for Manufacturing Control and Quality Control of Drugs" as a standard to which manufacturers should conform by the Ordinance of the Ministry of Health, Labour and Welfare, and Regulations were implemented in September 1980.

The legal position surrounding "Regulations for production Control and Quality Control of Drugs" was changed after the revision of the Pharmaceutical Affairs Law in April 1993. Previously informal standards which manufacturers were recommended to follow were extended, in April 1994, to legal requirements for manufacturer licensing. According to the revision, licensing for manufacturing pharmaceuticals cannot be obtained without the agreement of GMP.

Based on the intent of the GMP, the Osaka Prefectural Government, taking into consideration a stable supply of drugs and technical levels of the manufacturers, has repeated its discussions with individual manufacturers and their trade organizations since the initial formulation of the GMP in 1974, in order to contribute to the smooth implementation of it. In recent years, there has been an enormous progress in the manufacturing technique of drugs as well as in the move toward standardizing drug production internationally. We are taking such a drastic change into consideration in promoting the GMP.

2. The History of the GMP (See Attachment Ⅰ.)

We are going to briefly describe the history of the GMP in Japan and the responses of the Osaka Prefectural Government to the GMP requirements. In 1969, the WHO recommended the adoption of a GMP for drugs. In 1972, a GMP study project team was established in the Ministry of Health and Welfare (now Ministry of Health, Labour and Welfare) of Japan. In 1973, the Japan Pharmaceutical Manufacturers Association (JPMA) voluntarily made public the "Good Practices in the Manufacture and Quality Control of Drugs" Code (a voluntary code of practices). The companies which exported their drugs to Europe and United States, in particular, took active steps towards the adoption of such a code. In April, 1974, the Ministry of Health and Welfare (now Ministry of Health, Labour and Welfare) announced its draft GMP

document. In September, 1974, the Ministry of Health, Labour and Welfare issued a notification entitled the "Good Practices in the Manufacturer and Quality Control of Drugs" (official standards) (GMP), after necessary modifications were made in the first draft, based on the opinions of the metropolitan and prefectural governments and the industrial community.

Later, the Ministry provided more specific information by issuing a notification on the enforcement rules, etc. In order to encourage the smooth operation of GMP. In April, 1976, the GMP was put into effect in the form of an administrative guidance.

In October, 1979, when the Pharmaceutical Affairs Law was about to be partially amended, necessary articles of the Law were revised to integrate hardware and software aspects on the GMP into the Law, so the GMP came to have a place in the Law. On September 30, 1980, the amended Law was enacted. Since April 1994, whether a drug production approval can be awarded has been examined also in view of the GMP System for both of pharmaceutical preparations and original drugs.

20 the number of manufacturing sites of pharmaceuticals as of March 1995 is as follows.

In the meantime, the Prefectural Government of Osaka, which is proud of position as Japan's largest manufacture of pharmaceuticals (in terms of production value), has been sending its employees to the Ministry of Health, Labour and Welfare up to now, in order to develop inspectors to be assigned exclusively to GMP inspections.

In the area of guidance for the industry, when the Ministry's draft GMP was made public in 1974, the Osaka Prefectural Government held frequent lecture meetings for all of the drug manufacturers in the Prefecture, in order to explain the contents of the GMP and the necessity of its implementation. In addition, the prefectural government held study meetings for different trade organizations, such as the Osaka Pharmaceutical Products Association and the Osaka Home Drugs Association, at which it discussed the GMP concept and answered questions. The Osaka Prefectural Government submitted the results of these discussions and its opinions on necessary matters among the requests expressed by trade organizations, etc. to the Ministry.

In parallel with holding such study meetings, the Osaka Prefectural Government prepared a GMP Check Sheet and conducted a preliminary survey of GMP-applicable manufacturers, using the self-evaluation method, in order to identify their present status. In the process of this survey, the government collected the Sheet, checkd the information on the Sheet, and used the data as an indicator for future GMP guidance. Moreover, it conducted field surveys at all of the relevant facilities using the Check Sheet. Then, it held hearings with 165 facilities, discussed the problems with their top management and product security pharmacists, and gave them the necessary guidance to improve their situation. (See Attachment Ⅰ ①)

For three years since 1976, the Osaka Prefectural Government has worked to promote the GMP, using a self-evaluation technique based on the "Drug Manufacturer's List of Self-Inspection for Conformity to GMP Requirements", which the National Government presented, and the Improvement Plan Sheet. (See Attachment Ⅰ ②)

In the meantime, there were GMP applicable manufacturers in the Prefecture who did not belong to

any trade organization (so-called "outsiders"). In1977, the Osaka Prefectural Government brought them together, and encouraged them to organize an organization of their own. Promotion of the GMP and publicity on various notifications, etc. have been conducted through trade organizations since then, to attain a more thorough familiarization with the information.

In June, 1979, after the aforementioned List was submitted by the manufacturers to the Osaka Prefectural Government, it conducted field surveys to identify the progress, and provided guidance on specific improvement plans for less advanced facilities. The Prefectural Government offered administrative guidance energetically by holding improvement case presentation meetings at various companies, etc. (See Attachment Ⅰ ③)

Along with the legislation of the GMP in 1980, the Osaka Prefectural Government conducted two series of inspections of drugs manufacturers from 1980 to 1983, and encouraged them to thoroughly implement GMP, in an attempt to accomplish the complete achievement of the goals of the GMP as early as possible in the Prefecture. By the end of this period, we believe that the relevant facilities reached the prescribed level of hardware and software requirements at last. (See Attachment Ⅰ ④)

The Osaka government, dividing pharmaceutical manufacturing plants into groups according to dosage forms and components, conducted an on-the-spot survey during the period 1984 through 1992. (See Attachment Ⅰ ⑤)

Depending on the form of pharmaceutical product, these were natural differences in manufacturing management and quality control. There were also common problems within each group. Accordingly, surveys at their respective levels were conducted, and based on these results, guidance was given to each of the separate groups.

The Methods

1) Preparation of a Check Sheet Suited to Each Group

Check items necessary for each groups' needs are added to the Drugs Manufacturer's List of Self-Inspection for Conformity to the GMP Requirements (The Inspection and Guidance Division of the Pharmaceutical Affairs Bureau Notification No.42 issued on May 25, 1983). The additional items for injections, for example, include the environmental condition maintenance method for manufacturing rooms and its check method, and the sterilization method and its validation. Those for antibiotics include negative pressure control and the check of the residual concentration of penicillin at the time of changing product items to be manufactured in the same manufacturing rooms, for prevention of cross-contamination.

2) On-the-Spot Inspections and Guidance

On-the-spot inspections and guidance were conducted based on the GMP Inspection Model (See Attachment Ⅱ.).

3) Individual Guidance

If there were any non-compliance item(s) as a result of an on-the-spot inspection, we have pointed out the key points at that time of giving comments, and asked the manufacturer to improve on that

item.

4) Group Guidance

After the inspection of one entire group had been concluded and improvement reports were submitted, we summarized the individual companies' reports to compile one group report. Later, we held lecture meetings for the relevant facilities, using this group report, and provided guidance on what is an ideal situation and desirable future direction as a group. We submitted this group report to the Ministry of Health and Welfare (now Ministry of Health, Labour and Welfare) as well.

If we deemed it necessity, we might conducted another on-the-spot inspection for the same facility again before the following series of inspections were conducted.

In April 1995, most of the authorities to award approvals related to pharmaceutical manufacturers were transferred from the Minister of Health, Labour and Welfare to the Prefectural Governors. Then, the Prefectural Governments as accreditation agencies have pursued efforts of the quality control administration as one of their critical services.

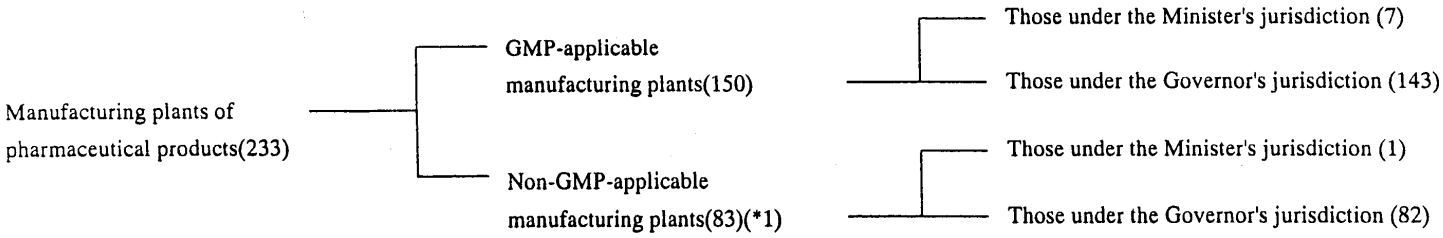
As most of Osaka's manufacturers' license required renewal at the end of 1996, on-the-spot surveys were conducted at all facilities needing renewal over the two-year period starting 1995. At that time, if any inadequacies were discovered, instructions for improvements were distributed, and a detailed plan for improvements was demanded. Upon receipt of an improvement completion report, the contents of the improvements were re-evaluated. As a result, in the end of 1996, the 181 manufacturing facilities in Osaka, to which the GMP is applicable, have all attained the pass standard. (See Attachment Ⅰ ⑥)

As validation was introduced as a license requirement in April, 1996, at present, guidance centered on validation in particular, is being carried out.

In order to harmonize with the WHO's new GMP (announced in April 1992), in addition to validation, "Education Practice", "Collection and Disposal" and "Self-Inspection" have been established as GMP software, and guidance regarding these practices is being carried out.

As of the end of March 2002, the number of manufacturing plants making pharmaceutical products is as follows.

《Composition of pharmaceutical manufacturers》



*1: particulars.

- In-vitro diagnostic reagents
- Gauze and absorbent cotton (excluding sterilized products)
- Various gasses for medial purposes
- Insecticides for the prevention of epidemics
- Powder or shredded herb medicines
- Others

(Attachment I)

The GMP Implementation Process in Osaka

Fiscal year	Ministry of Health, Labour and Welfare	Osaka Prefectural Government	Survey date	No. of GMP applicable manufacturers	Survey results	Remarks
1974	· Sept. 14, '74: The Pharmaceutical Affairs Bureau(PAB) Notification No. 801 was Issued. --"Good Practices in the Manufacture and Quality Control of Drugs"					The number of drug manufacturers as of Apr. 1, '74 Total 353 GMP applicable Manufacturers 211 GMP non-applicable 142
1975	· Apr.1, '75: the PAB Notification No.297 was issued. --"GMP Enforcement Rules"					
	· Apr.5, '75: The PAB/Inspection and Guidance Division(IGD) Notification No. 45 was Issued. --"the Drug Manufacturer's List of Self-Inspection for Conformity to the GMP Requirements"(The GMP Conformity List	· June 10, '75: The Osaka Prefectural Government (OPG) requested manufacturers to conduct self-inspections, using the GMP Check Sheet.				
	· Dec. 27, '75: The PAB/IGD Notification No. 150 was issued. --"The GMP Conformity List and Submission of the Improvement Plan Sheet"(The first issue)	· OPG conducted preliminary surveys(OPG's original activity).	Sept. 25-Nov. 25, '75	211	A: 15 (7.1%) B: 100 (47.6%) C: 95 (45.2%) (OPG could not survey a manufacturer.)	A: Almost completed GMP conformity work B: Partially completed C: Incompleted
1976		· OPG conducted hearings from manufacturers.	Feb. 2-24, '76			165 manufacturers in "B" and "C" ···①
		· Apr. '76: OPG reported the results of tabulation of the GMP conformity List to the National Government.	Apr. 15, '76	207	A: 92 (44.4%) B: 99 (47.8%) C: 16 (7.8%)	Self-evaluation by manufacturers ···②

Fiscal year	Ministry of Health, Labour and Welfare	Osaka Prefectural Government	Survey date	No. of GMP applicable manufacturers	Survey results	Remarks
1977	· May 9, '77: The PAB/IGD Notification No. 39 was issued. --"The GMP Conformity List and Submission of the Improvement Plan sheet"(The second issue)	· Sept., '77: OPG reported the results of tabulation of the GMP Conformity List to the National Government.				
1978	· Dec. 23, '78: IDG Notification No. 170 was issued. --"Submission of the GMP Conformity List(the entire list)"	· Sept., '78: OPG directed manufacturers to submit the GMP Conformity List OPG's original activity). · Nov., '78: OPG tabulated the results of the GMP Conformity List. · Jan., '79: OPG reported the results of tabulation of the GMP Conformity List to the National Government.	Oct. 1, '78	198	A: 127 (65.1%) B: 58 (29.8%) C: 10 (5.1%) (OPG could not survey three manufacturers.)	Self-evaluation by manufacturers
1979	· May 14, '79: The PAB/IDG Notification No. 62 was issued. --"the GMP Conformity Status Survey"	· Sept., '79: OPG reported the results of the survey to the National Government.	June 1, '79	188	A: 95 (53.4%) B: 19 (10.7%) C: 7 (3.9%) D: 57 (32.0%) (OPG could not survey 10 manufacturers due to either suspension or planned closure, of business.)	Self-evaluation by manufacturers and field surveys by OPG A:Completed GMP conformity work B:Almost completed C:Partially completed D:Incompleted
1980	· Aug. 16, '80: The Ministry of Health and Welfare(MHW) Ordinance No. 31 was issued. --"The Regulations for Manufacturing Control and Quality Control of Drugs"(the software aspect of the GMP) · Sept. 30, '80 : This Ordinance was put into effect.					

···③

Fiscal year	Ministry of Health, Labour and Welfare	Osaka Prefectural Government	Survey date	No. of GMP applicable manufacturers	Survey results	Remarks
1981		・OPG conducted the first series of field surveys on the GMP.	July, '80-Aug., '81	178		
1982		・OPG conducted the second series of field surveys on the GMP.	Sept., '81-Aug., '83	174		
1983						
1984		・OPG conducted on-the-spot inspections by group.		(No, of inspected facilities)		…⑤
		Crude drug preparations manufacturers	Oct., '84-Jan., '85	58		
		Antibiotics (oral) manufacturers Osaka ICHIGO Association	Nov., '84-Jan., '85	19		
		Joint Testing Labouratory Member Manufacturers	Feb.-Mar., '85	18		
1985		・OPG conducted on-the-spot inspections by group.	Oct., '85-Jan., '86	(The same as above)		
		Sterile preparations manufacturers		24		
1986		・OPG conducted on-the-spot inspections by group.		(The same as above)		
		Japanese Pharmacopoeia listed drugs manufacturers	Apr., '85- Apr.,'86	16		
		Ointments manufacturers	Sept.-Dec., '86	44		
		Steroid hormone preparations manufacturers	Sept.-Dec., '86	24		
		Manufacturers who violated the regulation in the past five years	Oct., '86-Feb., '87	35		

Fiscal year	Ministry of Health, Labour and Welfare	Osaka Prefectural Government	Survey date	No. of GMP applicable manufacturers	Survey results	Remarks
1987		· OPG conducted on-the-spot inspections by group.		(The same as above)		
		Bulk drug products manufacturers	May-July, '87 Aug.-Oct., '87	52		
		Oral solid preparations, and external liquid preparations manufacturers		60		
1988		· OPG conducted on-the-spot inspections by group.		(The same as above)		
		Crude drugs and Chinese medicine extracts manufacturers	June – Sept., '88	40		
		Medical gases manufacturers	Sept.-Oct., '88	26		
		Drug importers	Nov., '88-Feb., '89	117		
1989		· OPG conducted on-the-spot inspections, by group.		(The same as above)		
		JP-listed purified water manufacturers	Oct.-Nov., '89	10		
		Insecticide manufacturers	Feb.1- mar.31, '90	20		
1990		· OPG conducted on-the-spot inspections by group.		(The same as above)		
		Galenical preparations manufacturers	July. '90	15		
		Bulk drug products manufacturers	Jan.-Mar., '91	42		
1991		· OPG conducted on-the-spot inspections, by group.		(The same as above)		
		Lyophilization Parenteral Preparations manufacturers	May – June, '91	15		
1992		· OPG conducted on-the-spot inspections, by group.		(The same as above)		
		Liquid Parenteral Preparations manufacturers	Sept.-Nov., '92	13		
1993	· April 28, 1993 Article 27 of the Law (Requirement of approval of GMP systems)					

Fiscal year	Ministry of Health, Labour and Welfare	Osaka Prefectural Government	Survey date	No. of GMP applicable manufacturers	Survey results	Remarks
1994	・January 27, 1994 Notification of the MHW (applicable items of GMP systems) (GMP is applicable to active ingredient manufacturing plants) ・December 21, 1994 Government Ordinance No.399					
1995	・January 12, 1995 Notification of the Ministry of Health, Labour and Welfare (the authority to approve the execution of business was partly transferred to the Prefectural Governors), which came into effect on July 1, 1995.	・An on-the-spot survey of all facilities requiring license renewals at the end of 1996 was conducted	Apr., '95-Oct., '96	(The same as above) 165 (The same as above) 7		-Renewal of license:144 -Non-renewals:13 -Non-GMP targets:8 …⑥
1996	・April 1, 1996 Introduction of validation					
2000	・June 30, 2000 Validation criteria partly revised	・An on-the-spot survey of all facilities requiring license renewals at the end of 2001 was conducted	Aug., 2000-Sep., 2001	(The same as above) 132		-Renewal of license:121 -Non-renewals:11
2001						

(Attachment II)

The GMP Inspection Model

Ⅰ. Planning a GMP Inspection

We choose the facilities to be surveyed based on an intensive inspection by the National Government and our own annual on-the-spot inspections, etc. We review the inspection items by group, and prepare an inspection table.

In addition, we study the inspection period, the number of inspectors and the inspection method in advance, depending on the intended purpose of the inspection.

[Types of Inspections]

(1) Inspection for each group of preparations
(2) A survey on adulterated products
(3) General inspection according to the government direction
(4) Inspection for accrediting GMP compliance (pharmaceutical products for export)
(5) An inspection due to the renewal of a license or a change in buildings and facilities

Ⅱ. Preparation for GMP Inspections

Before conducting a GMP inspection, we prepare basic materials on the manufacturer to be inspected, and put together an outline of the manufacturer.

(1) Questionnaire sheets: These are the same ones which were used in the past to survey general information on the manufacturer, its licensed dosage form(s), and classification of drugs by efficacy.
(2) The facility file: This is the file in which we store the inspection list which was completed during the last on-the-spot inspection and the improvement report sheet of the manufacturer.
(3) Output file: retrieve data regarding previous on-the-spot conditions and descriptions of violations from computer data.

Ⅲ. Implementation of GMP Inspections

[Inspection Procedures]

(1) We meet with the product security pharmacist of the manufacturer to be inspected.
(2) We explain the contents of our work in the inspection, and discuss the inspection schedule. We usually spend one day to inspect the manufacturer.
(3) We hold the inspection of the manufacturer's premises.
(4) We summarize the inspection results and give our comments to the manufacturer.
(5) If there are any unsatisfactory items, we request the manufacturer to submit an improvement report.

Ⅳ. Inspection Results

In the case of inspections by group, we prepare a summary of the inspection results of the group. We identify the problems of the group at a lecture meeting for the entire group, as well as to offer guidance on improvement.

We file the inspection results and improvement reports in the individual manufacturers files to be used as reference date for future GMP inspections.

V. Specific Contents of GMP Inspections

1. To conduct an on-the-spot inspection of a manufacturer

(1) In the case of suspected GMP violation, on-site inspection of the manufacturing plant is conducted with no prior notification in principle.

(2) Two pharmaceutical inspectors usually conduct each inspection.

(3) When pharmaceutical inspectors visit manufacturers for inspections, they carry their identification cards with them, and show them if they are requested to do so.

(4) Pharmaceutical inspectors conduct inspections bearing in mind the central purpose of the inspections; to monitor the extent to which the manufacturer understands the GMP, and whether consistency between the hardware and software aspects of the GMP has been secured.

2. When meeting with a product security pharmacist

(1) We explain the inspection purposes and discuss the schedule.

(2) We use a copy of a renewal application form to check licensed product items and the floor plan of the manufacturer.

(3) Hearing of the outline of the manufacturer

We check the GMP organization, licensed dosage forms, major production items, and the product items manufactured on the inspection day, and we use the floor plan to check the flow of personnel and goods, and the contact situation between personnel and goods.

3. Items of GMP Inspection (Enacted: October 1990 by MHW, now MHLW) Reference Attachment

(→See next page)

Items of GMP Inspection

1. General matters

(1) Manufacturer

1. What characterizes the manufacturer as a company ?
2. Is the personnel concerned intent on understanding the Pharmaceutical Affairs Law ?
3. Does the manufacturer export ?
4. Does the manufacturer import ?

(2) Manufacturing plant

5. When was the manufacturing plant licensed under the Pharmaceutical Affairs Law ?
6. What characterizes the manufacturing plant ?
7. Does the manufacturing plant export ?
8. Has any of the exported products been returned for reasons involving quality and/or safety ?
9. Does manufacturing plant use any imported drugs ?

2. Specific matters

(1) Products to be Inspected for monitoring

10. What products are to be inspected ?

(2) Personnel

(2)-1. Personnel setup

(2)-1-1. Product security pharmacist

11. In the personnel setup required by GMP, is the product security pharmacist in a position superior to that of the manufacturing control manager and the quality control manager ?
12. In the case where the manufacturing plant has the deputy product security pharmacist, is it based on reasonable grounds and does the purview of his responsibilities stand clearly in a proper document ?

(2)-1-2. Manufacturing control manager

13. In the personnel setup required by GMP, is the manufacturing control manager put under the control of the product security pharmacist ?
14. Is the manufacturing control manager in a position enabling him to discharge his responsibilities without hindrance ?
15. In the case where the manufacturing plant has a deputy manufacturing control manager, is it based on reasonable grounds and does the purview to his responsibilities stand clearly in a proper document ?

(2)-1-3. Quality control manager

16. In the personnel setup required by GMP, is the quality control manager put under the control of the product security pharmacist ?

17. Is the quality control manager in a position enabling him to discharge his responsibilities without hindrance ?

18. In the case where the manufacturing plant has a deputy quality control manager, is it based on reasonable grounds and does the purview of his responsibilities stand clearly in a document ?

(2)-1-4. Relationship between the quality control unit and the manufacturing control unit

19. In the functional setup required by GMP, is the quality control unit independent of the manufacturing control unit ?

20. Are the quality control unit and the manufacturing control unit functioning on an equal footing ?

(2)-2. Discharging responsibilities

(2)-2-1. Product security pharmacist

21. Does the product security pharmacist do his control work on the spot ?

22. Does he decide whether to release products on the basis of exact understanding of how well manufacturing control and quality control of products are carried out ?

(2)-2-2. Manufacturing control manager

23. Is the manufacturing control manager a person other than the quality control manager ? Does he do his control work on the spot ?

24-1. Does he have the knowledge of the whole of the manufacturing control work ?

24-2. Does he handle properly blood preparations that do not constitute a lot ?

25. Are manufacturing directions prepared and issued on the basis of the product standard code, the manufacturing control standard code and the manufacturing hygiene control standard code ?

(2)-2-3. Quality control manager

26. Is the quality control manager a person other than the manufacturing control manager ? Does he do his control work on the spot ?

27. Does he have the knowledge of the whole of the quality control work ?

28. Does the manufacturing plant have testing protocols fitted for the actual manufacture there ?

(2)-2-4. Manufacturer

29. Does the manufacturer have anything to interfere with the product security pharmacist's responsibilities ?

30. Does the manufacturer give positive help to the product security pharmacist so as to have him discharge his responsibilities with ease ?

31. Does the manufacturer undertake education and training of the personnel of the manufacturing plant ?

(3) Buildings and facilities

32-1. Does the manufacturing plant as a whole conform to Article 5 and Article 5-2 of the

Regulations for Buildings and Facilities for Pharmacies etc. ?

32-2. Does the manufacturing room for weighing starting materials, preparing drug products and filling and sealing operations conform to Article 5 and Article 5-2 of the Regulations for Buildings and Facilities for Pharmacies etc. ?

32-3. In the case where drug products that are easy to disperse and cause anaphylaxis in very small amounts are manufactured, does the manufacturing plant conform to the prescribed standard ?

32-4. In the case where sterile preparations are manufactured, does the manufacturing plant conform to Article 6 of the Regulations for Buildings and Facilities for Pharmacies etc. ?

32-5. In the case where biological preparations are manufactured, does the manufacturing plant conform to Article 7 of the Regulations for Buildings and Facilities for Pharmacies etc. ?

32-6. In the case where blood preparations that do not constitute a lot are manufactured, does the manufacturing plant conform to Article 8 of the Regulations for Buildings and Facilities for Pharmacies etc. ?

32-7. In the case where radio pharmaceuticals are manufactured, does the manufacturing plant conform to Article 9 of the Regulations for Buildings and Facilities for Pharmacies etc. ?

33. Are cleanliness etc. in the manufacturing plant laid out appropriately in grades ?

34. Is the air-conditioner of the manufacturing plant installed appropriately ?

35. Is there any problem about the lines of flow of workers and things in the manufacturing plant ?

36. How is the whole environment controlled ?

37. Are the manufacturing facilities necessary for the manufacture of the products to be installed in order ?

38. Are the testing facilities necessary for the testing of the products to be installed in order ?

39. Are the manufacturing facilities and apparatuses etc. checked regularly to keep them in order ?

(4) Manufacturing hygiene

40. Are cleaning and washing carried out properly ?

41. Is cleaning work carried out according to the prescribed procedure ?

42. Are the working personnel educated in manufacturing hygiene ?

43. Are personnel other than those engaged in manufacturing kept off the manufacturing area ?

(5) Preparation and arrangement etc. of documents

(5)-1. Drug product standard code

44. Is the drug product standard code prepared to cover all the licensed products ?

45-1. Are the required matters carried in it ?

45-2. In the case where blood preparations that do not constitute a lot are manufactured, are all the necessary entries made in the drug product standard code ?

46. Is the drug product standard code used properly ?

47. Are necessary revisions and regular reviews made and measures to prevent errors taken ?

(5)-2. Manufacturing control standard code

48-1. Does each manufacturing plant have a manufacturing control standard code covering necessary matters ?

48-2. In the case where pharmaceutical products that are easy to disperse and cause anaphylaxis in very small amounts are manufactured, are all the necessary matters covered in it ?

48-3. In the case where sterile preparations are manufactured, are all the necessary matters covered in it ?

48-4. In the case where blood preparations that do not constitute a lot are manufactured, are all the necessary matters covered in it ?

49. Is the manufacturing control standard code used properly ?

50. Are necessary revisions and regular reviews made and measures to prevent errors taken ?

(5)-3. Manufacturing hygiene control standard code

51. Does each manufacturing plant have a manufacturing hygiene control standard code covering necessary matters ?

52. Is the manufacturing hygiene control standard code used properly ?

53. Are necessary revisions and regular reviews made, and measures to prevent errors taken ?

(5)-4. Quality control standard code

54-1. Does each manufacturing plant have a quality control standard code covering necessary matters ?

54-2. In the case where pharmaceutical products that are easy to disperse and cause anaphylaxis in very small amounts are manufactured, are all the necessary matters covered in it ?

54-3. In the case where sterile preparations are manufactured, are all the necessary matters covered in it ?

55. Is the quality control standard code used properly ?

56. Are necessary revisions and regular reviews made, and measures to prevent errors taken ?

57. In the case where testing is not conducted at the relevant manufacturing plant, is the measure referred to in it ?

(5)-5. Manufacturing directions

58-1. Are all the necessary matters covered in the manufacturing directions ?

58-2. In the case where blood preparations that do not constitute a lot are manufactured, are all the necessary matters covered in it ?

(5)-6. Testing protocol

59. Are all the necessary matters covered in it ?

(6) Arrangement and retaining of records

(6)-1. Records of manufacturing control

60. Does the record show that manufacture was carried out according to the manufacturing directions ?

61-1. Is the record of manufacturing prepared for each lot ?

61-2. In the case where biological preparations are manufactured, are all the necessary matters recorded ?

61-3. In the case where blood preparations that do not constitute a lot are manufactured, are all the necessary matters covered in it ?

62. Are receipts, supplies and storage of starting materials, in- process materials, drug products and labeling and packaging materials recorded as prescribed in the drug product standard code and the manufacturing control (manufacturing hygiene control) standard code ?

63. Is manufacturing control checked by the manufacturing control manager ?

64. Are there records that the manufacturing control manager checked the propriety of manufacturing control ?

65. Does the manufacturing control manager report in writing to the product security pharmacist that manufacturing control was properly implemented ?

66. Is it recorded that the product security pharmacist checked such report ?

(6)-2. Records of quality control

67. Is it on record that testing was conducted on the basis of the quality control standard code and the testing protocol ?

68-1. Are results of quality control recorded for each lot or control unit ?

68-2. In the case where blood preparations that do not constitute a lot are manufactured, are necessary test results recorded ?

69. Are test results recorded as prescribed in the quality control standard code ?

70. Are the methods of testing and the method of evaluating test results right ?

71. Are raw date retained ?

72. Are there records of checking the testing facilities to keep them in order ?

73. Are there records of stability testing of products ?

74. Are qualities of test reagents known through the records of preparation, records of testing, etc. ?

75. Does the person in charge of testing check such records ?

76. Are there records that the quality control manager evaluated test results ?

77. Does the quality control manager report in writing on test results to the product security pharmacist and the manufacturing control manager ?

78. Did the product security pharmacist and the manufacturing control manager check what was reported in writing by the quality control manager ?

(6)-3. Maintenance of records

79. Are records of manufacture, storage, receipts and supplies and manufacturing hygiene retained for the prescribed periods of time ?

80. Are such records kept available for ready reference ?

81. Are records of testing retained for the prescribed periods of time ?

82. Are such records kept available for ready reference ?

(7) Manufacturing operations

83. Are manufacturing operations carried out properly according to the prescribed procedures ?

84. Are starting materials, labeling and packaging materials, in- process products and drug products handled properly according to each standard code ?

85. Are starting materials and drug products that do not conform to specifications handled as they should be according to each standard code ?

86. Are labeling and packaging materials handled properly ?

(8) Quality control work

87. Is the quality control work carried out properly according to the prescribed procedures ?

88. With regard to the items of tests that relevant manufacturing plant is not allowed to conduct, are the tests on them conducted elsewhere according to the procedures prescribed in the quality control standard code ?

89. Are reference products preserved in proper condition according to the product standard code, the quality control standard code, etc. ?

90. Are reference products preserved in adequate amounts for the prescribed periods of time according to the product standard code, the quality control standard code, etc. ?

(9) Release of products

91. Are products released and distributed properly ?

92. In the case where finished products are transported to the distribution center before their tests have been completed, are they put under proper control at the distribution center ?

(10) Complaints procedure

93. Is any system established to cope with complaints rapidly ?

94. Are any measures taken to investigate the causes of complaints and to remedy them (including replacements, returns, recalls etc.) by coping with them rapidly ?

95. Do all the manufacturing plants keep records of complaints procedure involving quality of drugs ?

96. Does the record of complaints procedure cover all the necessary matters including checking of complaints procedure by the product security pharmacist ?

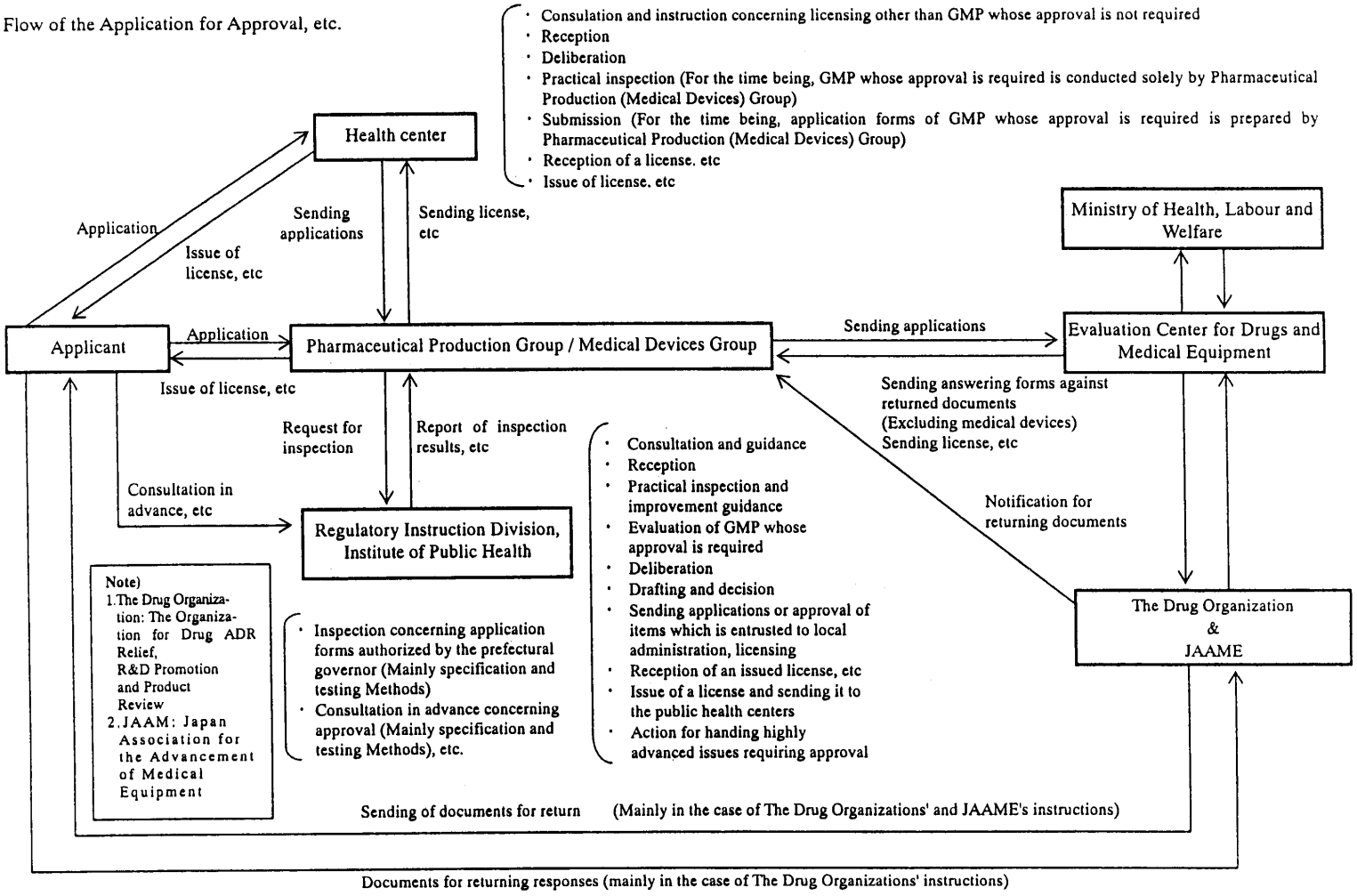
97. Is the record of complaints procedure retained for three years from the date of its preparation ?

Addition

Is validation properly conducted?

(Reference 12)

Flow of the Application for Approval, etc.



Drugs, etc. To Be Approved by Prefectural Governments

Ⅰ. Approval-Related Items

	Fiscal year	#	Date of deligation	Name of the group of drugs exhibiting the same effects, etc.	Remarks
Drugs	1970	1	Nov. 1, 1970	Cold medicines	
	1972	1	Jan. 1, 1973	Antipyretics/analgesics	
	1984	2	Jun. 1, 1984	Antitussives/expectorants	
			Ditto	Purgatives	
	1985	1	Apr. 1, 1985	Antivertigo drugs	
	1986	2	Apr. 1, 1986	Medical gases	(Liquid oxygen, liquid nitrogen, and nitrous oxide)
			Aug. 1, 1986	Ophthalmologic drugs	
	1988	2	Apr. 1, 1988	Formulations with vitamins as main ingredients	
			Ditto	Enemas	
	1989	1	Apr. 1, 1989	Anthelmintics	
	1991	1	Apr. 1, 1991	Nasal drops for nasitics	
	1995	1	Jun. 1, 1993	Oral drugs for nasitics	
	1995	2	Apr. 1, 1989	Gastrointestinal drug/	
			Ditto	External drugs for the treatment of hemorrhoids	
	1998	1	May.15, 1998	Medications for athlete's foot and ringworm	
Quasi drugs	1985	2	Apr. 1, 1985	Sterile cotton	
			Ditto	Menstruation-related articles	
	1994	3	Jun.20, 1994	Hair dyes,	
			Ditto	Permanent wave agents,	
			Ditto	Medicated toothpastes	
	1999	2	Mar.31, 1999	Stomachic remedy	
			Ditto	Vitamin preparation	
Medical devices	1985	6	Apr. 1, 1985	Spectacles for vision correction	

The number of groups of drugs with the same drug effects

Ⅱ. License-Related Items (excluding things required for some pharmaceuticals)

1. Business licensing
2. The renewal of licensing
3. The renewal of license certificates
4. The resistance of license certificates
5. Supplementation (change) of the product item
6. The approval of managers
7. The notification of abolishment, etc.

" No Drug Abuse" 5-year Project in Osaka Prefecture, (Drug Abuse Eradication Campaign)

Objectives

Our society faces a serious situation of the 3rd Period of Drug Abuse that has expanded to the juveniles. Thus, countermeasures of enlightenment, prevention from recommitting, and rigid enforcement of the regulations shall be reinforced to end the 3rd Period within 5 years.

3 Strategies and 26 Tactics

I. Enlightenment activity is aggressively promoted to prevent the juveniles from abusing drugs.

A. To systematize civilian organizations to enlighten the juveniles not to abuse drugs
B. Training of instructors by volunteers for prevention of drug abuse
C. To instruct primary school children about drug abuse
D. To rigorously educate junior and senior high school students about drug abuse
E. To enlighten working youths and college students
F. To deepen and expand enlightenment of parents
G. To induce enlightenment caravan cars to Osaka for prevention of drug abuse
H. To promote internal communication with Asian countries for prevention of drug abuse
I. To promote the enlightening activities in collaboration with mass media
J. To research and investigate the effective enlightening methods

II. Extensive fulfillment of consultations and medical cares for prevention from recommitting of drug abuse

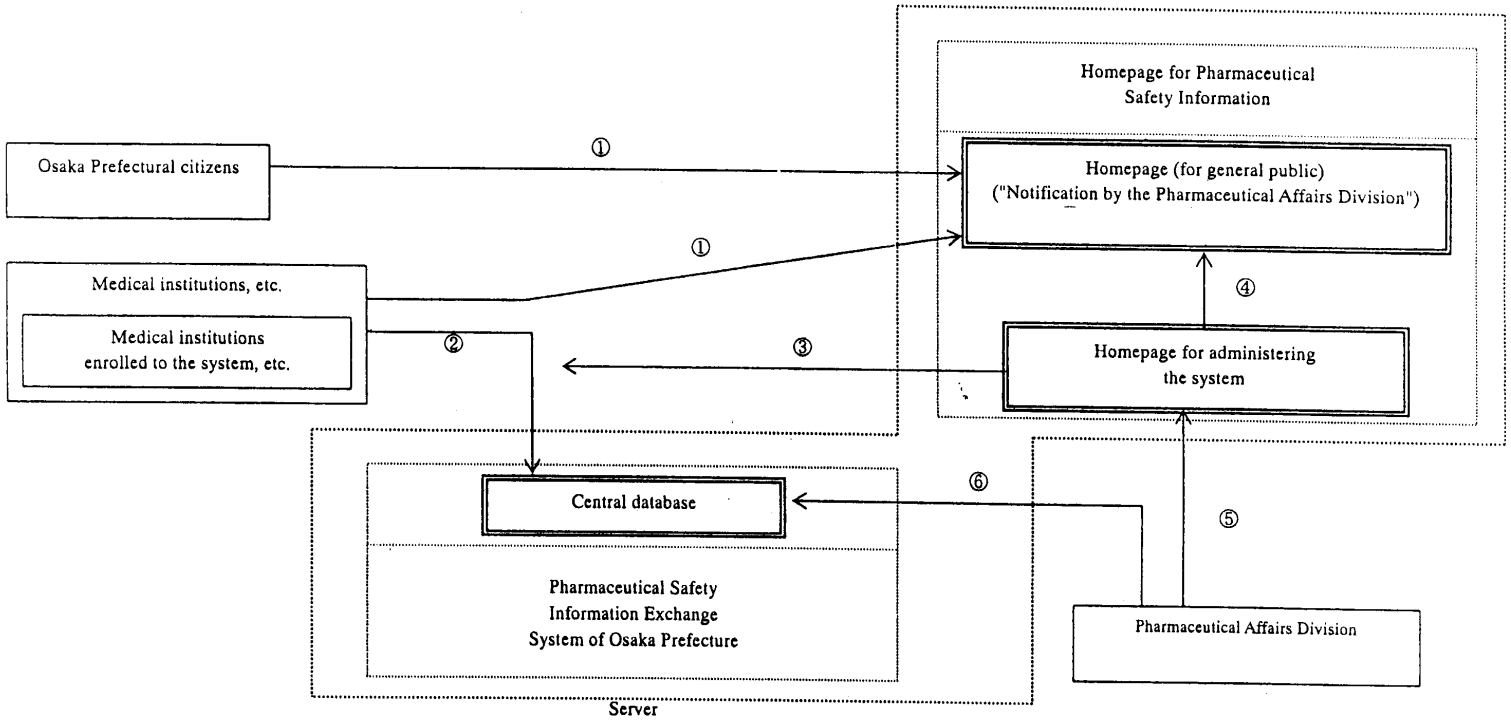
K. To deepen and expand consultation contents at the health center
L. To deepen and expand consultation duties of the juvenile protection and guidance center
M. To upgrade and expand the system for consultation and medical examination at the integration center for sound mind, etc.
N. Arrangement of preparedness to receive addicts
O. Arrangement of networks with civilian medical institutions
P. Exhaustive education to prevent from recommitting drug abuse during rehabilitation
Q. Collaboration of the self-helping groups from drug dependence
R. To deepen and expand consultation duties of addict consultants
S. Expansion of the drug abuse-preventing activity-supporting teams
T. To research the therapeutic manuals
U. To investigate systems for rehabilitation

III. Exhaustive and rigid enforcement of regulations to root out violations

V. Exhaustive and rigid enforcement of regulations for illicit traffic organizations
W. Exhaustive and rigid enforcement of regulations for smuggling
X. International collaboration with the related agencies in foreign countries to watch and enforce the regulations
Y. To exhaustively expose the drug-abusing criminals including juveniles
Z. Exhaustive supervision of agencies with license

(Reference 15)

The Information Exchange System for Drug Safety in Osaka Prefecture



① Reference for the homepage (freely accessible)
② Use of the system (only by the medical institution)
③ Authorization and cancellation of medical institution enrollment
④ Writing/deletion/correction on the homepage, "Notification by the Pharmaceutical Affairs Division"
⑤ Administration/use of the homepage for administering the system (only by Pharmaceutical Affairs Division)
⑥ Analysis of the information

(Reference 16)

Blood Donation Promotion Organization of Osaka Prefecture

Blood Donation Promotion Organization in Osaka Prefecture

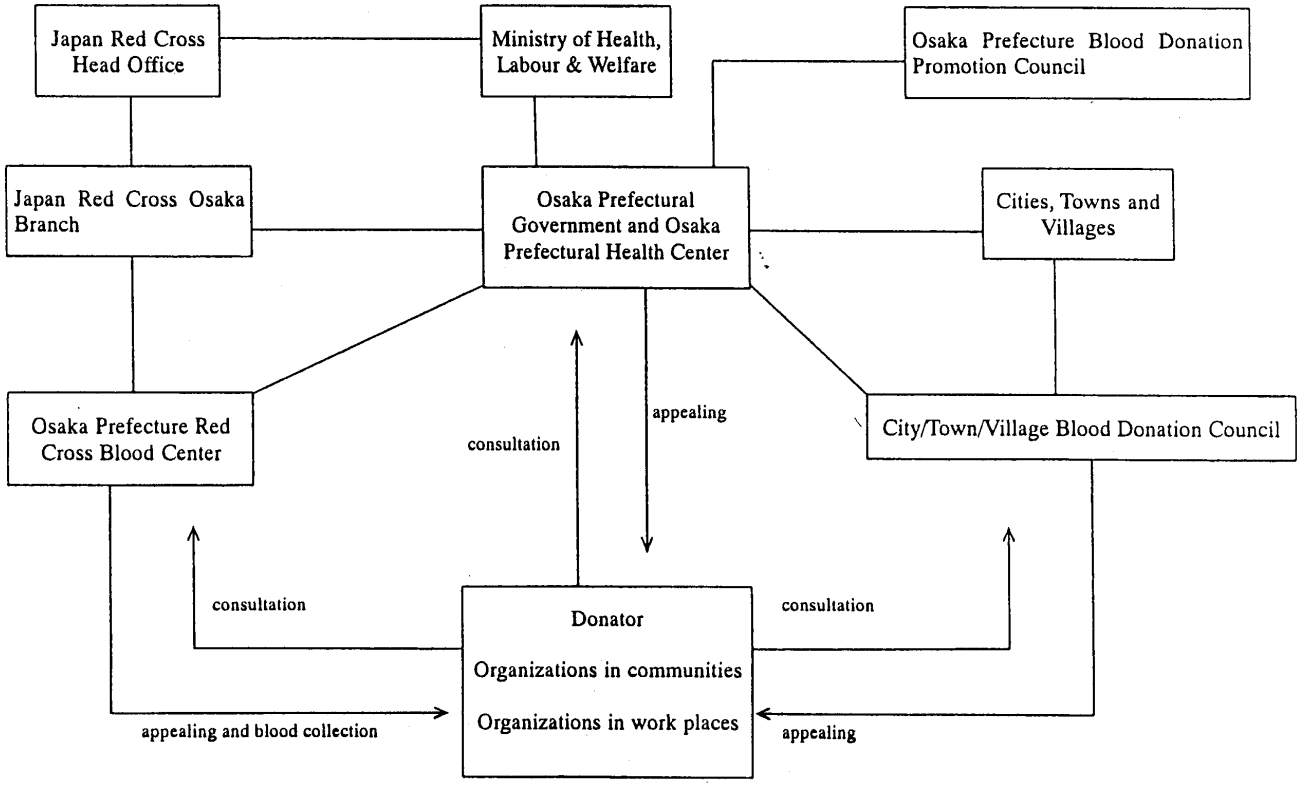
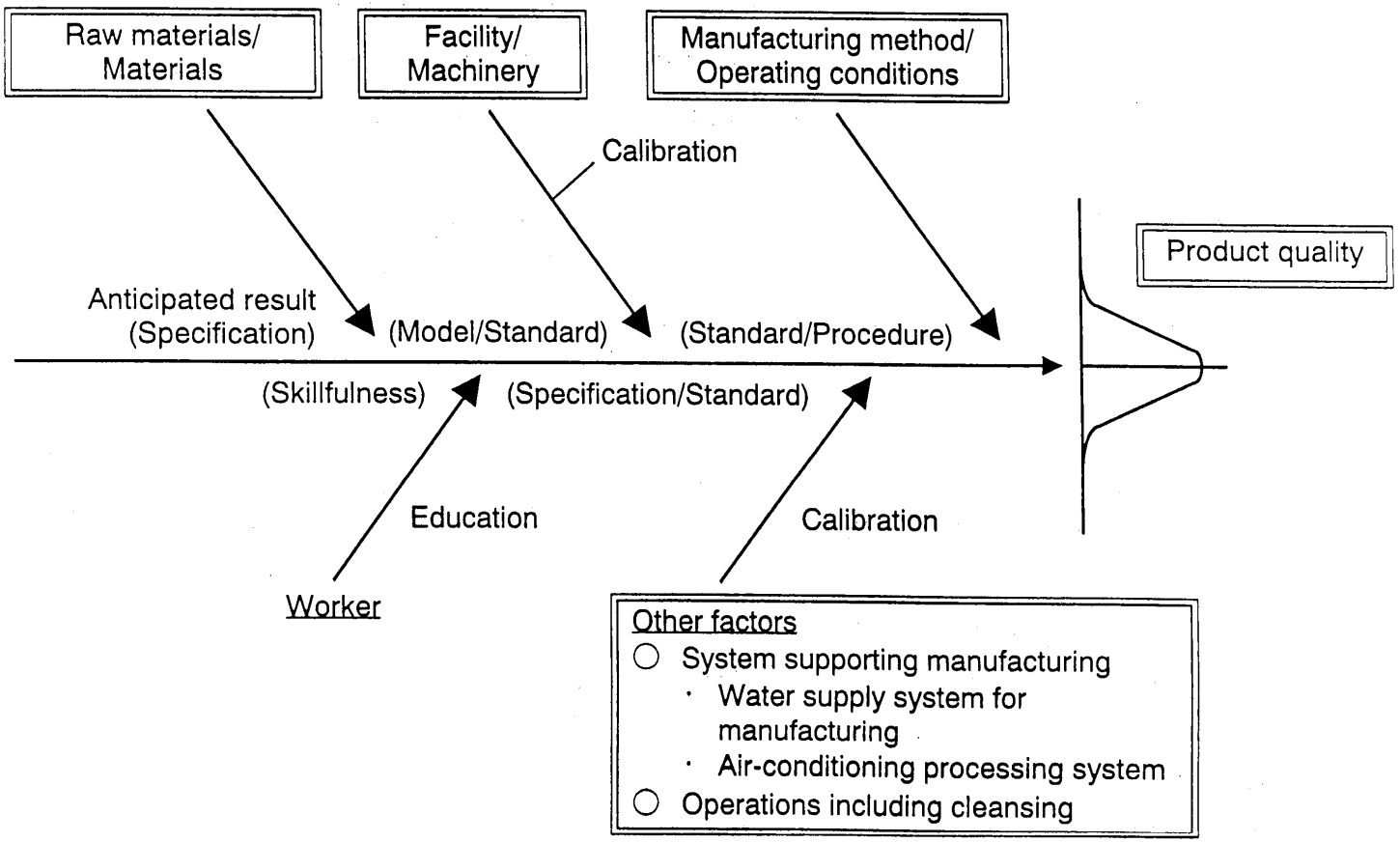


Chart of Property Factors Which Decides Quality of Drug Products

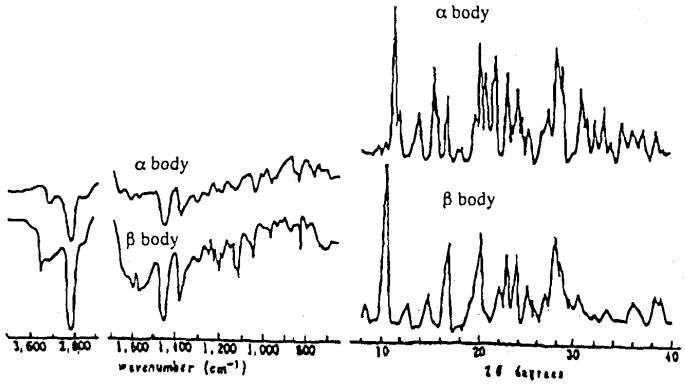


Stable Polymorph (α body) and Metastable Polymorph (β body)

Polymorph of chlortetracycline hydrochloride

α body　　β body

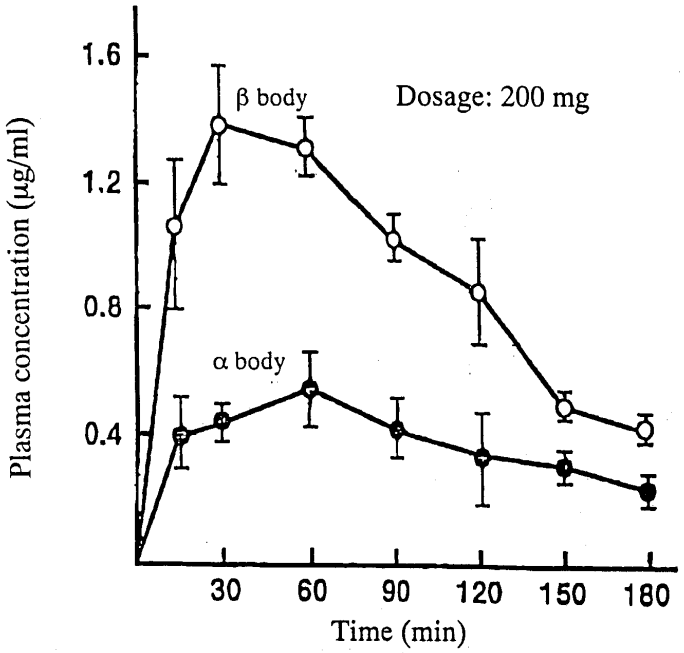
Microscopic view (×600)



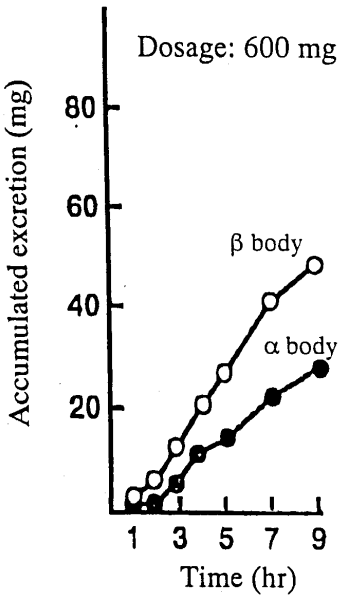
IR spectrum　　X-ray analysis pattern

Association between Crystal Polymorphism and Plasma Concentration/Urinary Excretion [Crystal polymorphism of chlortetracycline hydrochloride]

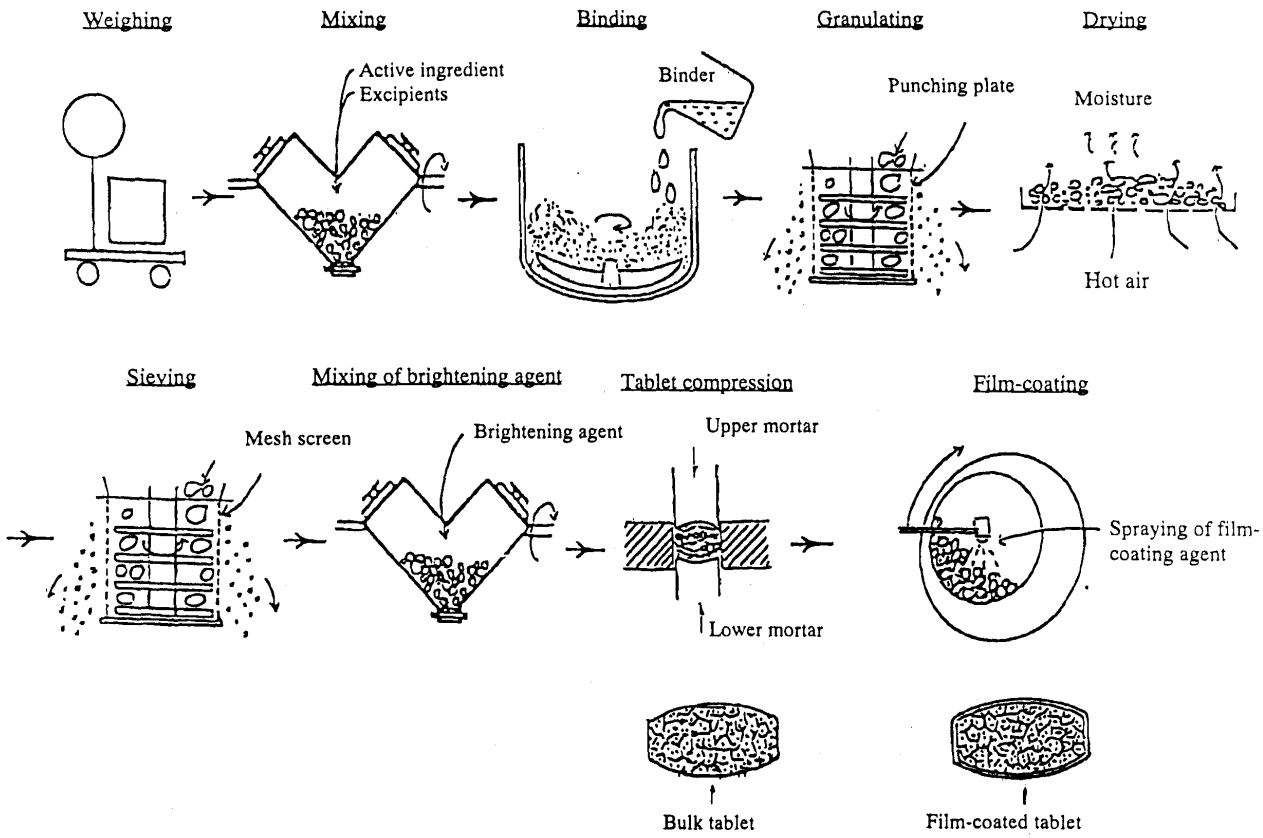
Plasma concentration resulting from duodenal administration in rabbits



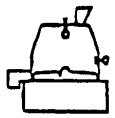
Urinary excretion accumulation curve resulting from peroral administration in humans



Schematic Drawing of Pharmaceutical Manufacturing Processes



Examples of Commonly Used Granulators

Model	General features of granules
Agitating granulator 	Heavy and circular granules Usable for processing the raw materials whose fluidization is inhibited by electrostatic adhesion
Fluidizing granulator 	Porous and soluble granules of 0.1 to 2mm in particle diameter Suitable for manufacturing minute granules or granules for manufacturing tablets
Extruding granulator 	Heavy and hard cylindrical granules of 0.5 to 3mm in particle diamter Usable for processing most of the raw materials
Centrifugal rotating granulator 	Heavy and circular granules Used for manufacturing most of the preparations with sustained release consisting of circular granules
Dry-milling granulator 	Granules with irregular shape of some mm or less in particle diameter Suitable for manufacturing the preparations whose moisture content affects stability of the quality of the raw materials Drying process is not necessary.

Regulations for Manufacturing Control and Quality Control of Ethical Extract Products in Kampo Medicine (Oriental Medicine) Formulations

(Self-imposed regulations of Japan Chinese-Medicine Manufacturers Association)

Chapter 1 General Provisions

<Purpose>

The purpose of the Regulations is to assure quality of ethical extract products in Kampo medicine formulations by establishing requirements for the manufacturing control and quality control, mainly of raw material crude drugs, in the manufacturing process for such products, and in conformity with the Regulations for Manufacturing Control and Quality Control of Drugs (hereinafter referred to as "GMP Regulations").

<Scope of application>

The Regulations shall apply to any manufacturing plant for ethical extract products in Kampo medicine formulations and to that for extracts for such products.

<Definitions>

The definitions contained in the Japanese Pharmacopoeia (JP), Standards for Non-pharmacopoeial Crude Drugs (Non-JP Crude Drug Standards) and the GMP Regulations shall be applicable to the general terms used in these Regulations. The following definitions of terms apply to these Regulations:

"Extract for Kampo medicine formulations" means an extract used as raw material for prescription extract products in Kampo medicine formulations.

"Designed quality" means a quality as described in the letter of manufacturing (import) approval of an extract for Kampo medicine formulations established in accordance with the standard decoctions stipulated in. "Requirements for Prescription Extract Products in Kampo Medicine Formulations" [PAB/ERD-2 Notification No. 120 (May 31, 1985)].

"Indicator ingredient" means an ingredient used as an indicator for the assurance of the equivalence of the extract for Kampo medicine formulations and finished product to the standard decoction.

"Self-determined ingredient" means an ingredient, other than the indicator ingredient, determined quantitatively by the manufacturer at his own discretion.

<Crude drug (or herbal material) control manager>

The manufacturer of the extract for Kampo medicine formulations, as stipulated in the GMP Regulations, shall designate a manufacturing control manager and a quality control manager under the product security pharmacist, and a crude drug control manager under the quality control manager.

The quality control manager may be at the same time the crude drug control manager.

1) The crude drug control manager shall have the following qualifications:
   (1) Having professional knowledge on crude drugs and an ability to form a qualitative judgment of crude drugs.
   (2) Having abundant knowledge from practical experience on the treatment of raw material crude drugs.
2) In order to provide practical quality assurance of raw material crude drugs, the crude drug control manager shall perform the following duties by himself, or if necessary, by a designated person.
   (1) Method of sampling of raw material crude drugs.
   (2) In the process of the analysis and testing of raw material crude drugs, evaluation of the results of differentiation (including differentiation of morphological quality).
   (3) Education and training of personnel handling raw material crude drugs.
   (4) Miscellaneous duties for the quality assurance of raw material crude drugs.

Chapter 2 Quality Assurance of Raw Material Crude Drugs

For the quality assurance of raw material crude drugs, there shall be the drug product standard code, manufacturing control standard code and quality control standard code, describing necessary matters in the light of JP, non-JP Crude Drug Standards, other official standards, related official notifications and the latest scientific levels, as well as the following matters:

<Drug product standard code>

1) Specifications and test method
   (1) For a crude drug containing an indicator ingredient and a self-determined ingredient, a method of determination and content limit of such ingredients shall be settled.
   (2) Grading test of cut crude drugs.
   (3) Differentiation test.
   (4) Any test deemed necessary in the light of related official notifications and the latest levels of science and technology, on a full understanding of the concept of the original text of Kampo medicine.
2) Requirements in the commission of cutting processing of crude drugs
   In addition to "Requirements for Commissioned Manufacture of Drugs etc." (PAB Notification No. 234, March 12, 1986), the following requirements shall be taken into consideration:
   (1) Before commissioning, the quality of whole crude drugs shall be assured on commissioning person's responsibility.

(2) Standards for receipt of cut crude drugs shall be established, and analysis and testing of such products shall be performed accordingly upon their receipt.

3) Requirements in purchasing cut crude drugs

When cut crude drugs are received, the quality of whole crude drugs shall be assured on the basis of the results of analysis and testing of whole crude drugs submitted by the supplier.

<Manufacturing control standard code>

1) Lot control (of whole land cut crude drugs)

The lot control shall be kept, in principle, by the unit of receipt. It shall also be kept by the place of production, packaging form, appearance, etc. of the crude drug, and, if necessary, the crude drug shall be controlled for each lot.

2) Storage control

(1) Appropriate standards for facilities, methods and conditions of storage shall be established and followed for prevention of contamination and deterioration due to fungi, insects, rodents, etc.

(2) Fumigation shall be performed according to JP General Rules for Crude Drugs.

The record of fumigation shall be retained for three years.

<Quality control standard code>

1) Method of sampling

An appropriate method of sampling for the analysis and testing shall be established for each crude drug in consideration of its conditions such as the place of production, appearance, distribution and packaging form.

2) Re-analysis and retesting

Raw material crude drugs (whole and cut), when stored for a long period, shall be stored in conformity with the standards of re-analysis and retesting established for that purpose in consideration of the properties of the crude drugs.

3) Retention of reserve samples of crude drugs

The reserve samples of crude drugs consisting of at least twice the quantity necessary for the analysis and testing required shall be retained for each lot under appropriate conditions for three years after the date of manufacture of the extract for Kampo medicine formulations.

4) The records shall be accumulated and kept in good order for the quality assurance of crude drugs.

Chapter 3 Manufacturing Control and Quality Control in the Manufacturing Process of Extract for Kampo Medicine Formulations

With good understanding of original texts of Kampo medicine, facilities for stable manufacture of extracts for Kampo medicine formulations equivalent to the designed quality described in the letter of manufacturing (import) approval shall be established; manufacturing conditions and methods fulfilling that purpose shall be devised; and the quality of the extract shall be assured in the light of the designed quality by a scientific evaluation.

In order to attain the above purposes, the drug product standard code, manufacturing control standard code, manufacturing hygiene control standard code, and quality control standard code shall be prepared, describing the following information:

<Drug product standard code>

1) Manufacturing method and process for each product
   "Method and process" in the above include the following information:
   Standard charge-in quantity, extraction condition, concentration and drying conditions, sieving, mixing conditions, storage conditions.
2) Amount and rate of yield in each manufacturing process
   (1) The range of the amount and rate of yield shall be given in consideration of raw material crude drugs and the production scale.
   (2) The assurance of designed quality of the manufactured extract for Kampo medicine formulations shall be verified.
3) Specifications and test method for the extract for Kampo medicine formulations

<Manufacturing control standard code>

1) Manufacturing control
   (1) Control of solvents for extraction.
   (2) Prevention of contamination.
   (3) Regulations for routine control and regular control.
   (4) Other matters concerning manufacturing control.
2) Requirements for a change in facilities, manufacturing method, etc.
   (1) Confirmation of designed quality.
   (2) Measures to be taken after confirmation and evaluation.

<Manufacturing hygiene control standard code>

1) Manufacturing hygiene control
   (1) Hygiene control of working personnel
   (2) Hygiene control of manufacturing room, facilities and utensils

<Quality control standard code>

1) Retention of reserve samples of extract for Kampo medicine formulations
   The reserve samples consisting of at least twice the quantity necessary for the analysis and testing required shall be retained for each lot under appropriate conditions for three years after the date of manufacture.

Chapter 4 Record of Manufacturing Process of Extract for Kampo Medicine Formulations

A record describing clearly the manufacturing control, manufacturing hygiene control and quality control shall be maintained, and it shall be retained for three years after the date of manufacture of the finished product with use of the extract. The matters to be recorded shall be selected in consideration of the matters required in the GMP Regulations; and the following matters shall be added:

1) Lot number and amount of raw materials

When raw material crude drugs in two or more lots are mixed, the lot numbers, amounts, as well as the composition (amounts of raw materials) shall be recorded.

When a previously mixed crude drug is used as raw material, a new lot number shall be assigned.

2) Recording matters in the manufacturing process of extract for Kampo medicine formulations
   (1) Weighing process
   (2) Extraction process

   Number of the extracting machine, charge-in quantity, amount of solvent for extraction, time for raising temperature, extraction temperature, extraction time.
   (3) Concentration process

   Number of the concentrating machine, concentration temperature, concentration time.
   (4) Drying process

   Number of the drying machines, drying temperature, drying time, amount of dried extract.
   (5) Other recording matters in each process

Chapter 5 Contract Between Manufacturer of Extract for Kampo Medicine Formulations and Manufacturer of Finished Product

In the case where the manufacturer of an extract for Kampo medicine formulations is not at the same time the manufacturer of the finished product, the manufacturers shall conclude a contract beforehand for supply and receipt of the extract, and establish standards concerning the following matters, so that the quality assurance of the extract is maintained.

1) Confirmation of the letter of approval of the extract
2) Manufacturing control of the extract

   Confirmation of the conditions of the manufacturing control.
3) Quality control of the extract
   (1) Presentation of the test method and establishment of the standards for supply and receipt.
   (2) Confirmation of the test results.
4) Transportation of the extract
   (1) Quality and form of containers and packaging materials.
   (2) Consideration shall be given for prevention of deterioration of the extract during transportation.
5) Supply and receipt of the extract
   (1) Record of supply and receipt shall be maintained by lot.
   (2) The manufacturer of the extract, when supplying the extract, shall attach the manufacturing process record of the extract after consultation with the manufacturer of finished product.

6) The manufacturer of finished product shall confirm, when necessary, records concerning manufacturing control, manufacturing hygiene control and quality control submitted by the manufacturer of the extract.
7) In preparation for doubt aroused about the quality, a liaison manager (in the quality control unit) shall be designated on both sides for the maintenance of close communication.
8) Records shall be retained for three years.

Chapter 6 Manufacturing Control and Quality Control of the Process of Preparation of Finished Products

In the process of preparation of finished products, the GMP Regulations and the Regulations for Buildings and Facilities for Pharmacies etc. shall be followed. At the same time, in consideration of the fact that the extract for Kampo medicine formulations is a rich nutritive source for microorganisms, manufacturing control shall be maintained with special attention being paid to the prevention of microbial contamination.

Chapter 7 Analysis and Testing of Finished Products

The quality assurance of finished products shall be maintained not only by the specifications and the analysis and testing described in the letter of approval, but also by the guidelines specially established in the light of the latest scientific level. At the same time, efforts should be made for the development of new evaluation method.

1) The tests required in addition to the specifications and analysis and testing in the letter of approval may include the following:
   (1) A quantitative test of ingredients under control other than ingredients conforming to the specifications for approval.
   (2) Microbiological test.
   (3) Physical test.
   (4) Other test.

Chapter 8 Complaints

As stipulated in the GMP Regulations, an appropriate measure shall be taken quickly upon receipt of a complaint. The manufacturer of the prescription extract product in Kampo medicine formulations shall investigate not only into his manufacturing plant, but also into the manufacturer of the extract for Kampo medicine formulations used and raw material crude drugs and the trader of the crude drugs, and take appropriate measures accordingly.

The record of complaints shall be retained for three years after the date of preparation of the record.

Chapter 9 Imported Products

Imported products shall be subject to the same regulations as those for the domestic products so that their designed quality is assured.

大阪家庭薬協会の紹介

平成12年10月

大阪家庭薬協会

はじめに

医薬品は国民の健康を保持・増進する上で必要不可欠なものであり、これに関係した業務に携わる者は、常に有効性に富み、より安全でかつ品質の高いものを世に提供することが義務付けられています。

大阪家庭薬協会の設立目的は、国民の健康維持増進に寄与すると共に会員共通の利益及び相互の親睦を図ることとされています。

これを受けて、平成８年４月には大阪家庭薬協会の組織及び役割機能の改革を実施し、活動を続けてきました。平成１２年３月までの４年間は改革の第１ステージと位置付けられます。この間、各委員会は活発な活動を行いその役割を十分に果たしてきたと考えています。

本冊子も協業化情報委員会の委員の皆様方のご苦労によって作成された貴重な資料であります。

平成１２年５月の定時総会において、改革の第１ステージを指揮された小林製薬株式会社の代表取締役社長である小林一雅氏が会長を退かれました。

小林前会長の引かれた改革路線をさらに深耕するため、平成１２年度からは改革の第２ステージとして位置付け、協会加盟企業のマイメリット及びアワーメリットをさらに追求することとなりました。

今回、会員の増減及び役員の変更があったことから、平成１２年度版「大阪家庭薬協会の紹介」を発刊致します。

会員企業の担当の皆様及び本冊子の作成に携わられた皆様の努力に対して、厚くお礼を申し上げます。

平成１２年１０月６日

大阪家庭薬協会
会長　森　輝彦

目　　次

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ロート製薬　会長

最高顧問理事

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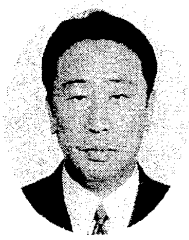
小林製薬　社長

会　長

森　　輝彦
丹平製薬　社長

副会長



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笹岡薬品　社長

副会長

柴田　　仁
大幸薬品　社長

理　事

森田　隆和
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森下　美恵子
森下仁丹　会長

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坂上　晴一
樋屋製薬　社長

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七ふく製薬 代表取締役

理　事

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常盤薬品工業　社長

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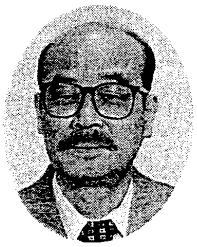
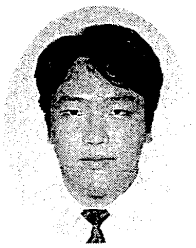


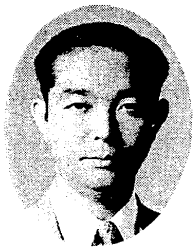
森　良幸
大杉製薬　常務

理　事



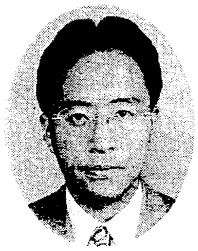
古田　耕
摩耶堂製薬　社長

監　事



藤井　隆太
龍角散　社長

監　事



横山　晴人
横山製薬　社長

顧　問

西脇　廣行
小林製薬

専務理事

三國　直世志
大阪家庭薬協会

平成１４年８月１日

大阪生薬協会案内

大阪市中央区伏見町２－４－６
ＴＥＬ　０６－６２０２－７８９８
ＦＡＸ　０６－６２０２－７８９８

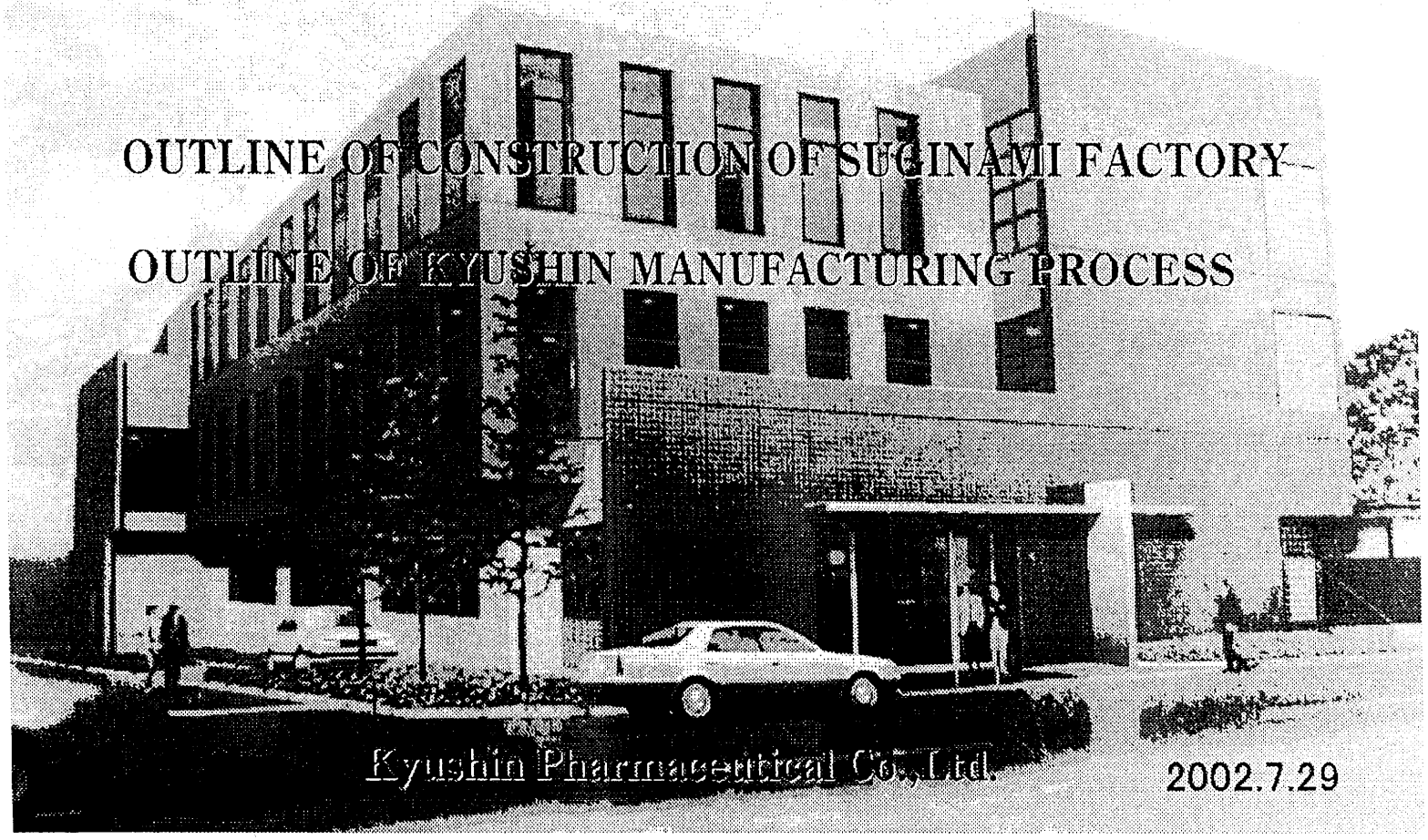
１．設立　大阪生薬協会は、近畿一円で生薬の医薬品製造、輸入販売及び卸売販売を行う関係業者によって昭和３３年２月１日に設立されました。

２．目的　生薬業の発展向上を図り会員相互の親睦並びに会員共通の利益を増進し、国民の保健衛生に寄与することを目的としています。

３．概況　平成１４年４月１日現在会員数は４１社となっています。
又、本町生薬会（１３社・東京）、愛知県生薬会（７社）、京滋生薬会（６社）、神戸生薬会（１社）と共に、日本生薬連合会を設立しています。

４．事業　（１）関係官庁並びに関係機関に対し意見の具申、陳情、連絡等をすること。
（２）関係法規等の公布、改廃並びに業界の必要事項等につき之を会員に連絡すること。
（３）生薬の振興に関し諸施策をなし又は他の機関等に協力すること。
（４）会員の親睦並びに啓発向上を図るため懇親会、研究会又は講習会等を開催すること。
（５）其他本会の目的を達成するため必要な事項。

PROFILE OF SUGINAMI FACTORY



OUTLINE OF CONSTRUCTION OF SUGINAMI FACTORY

OUTLINE OF KYUSHIN MANUFACTURING PROCESS

Kyushin Pharmaceutical Co., Ltd.

2002.7.29

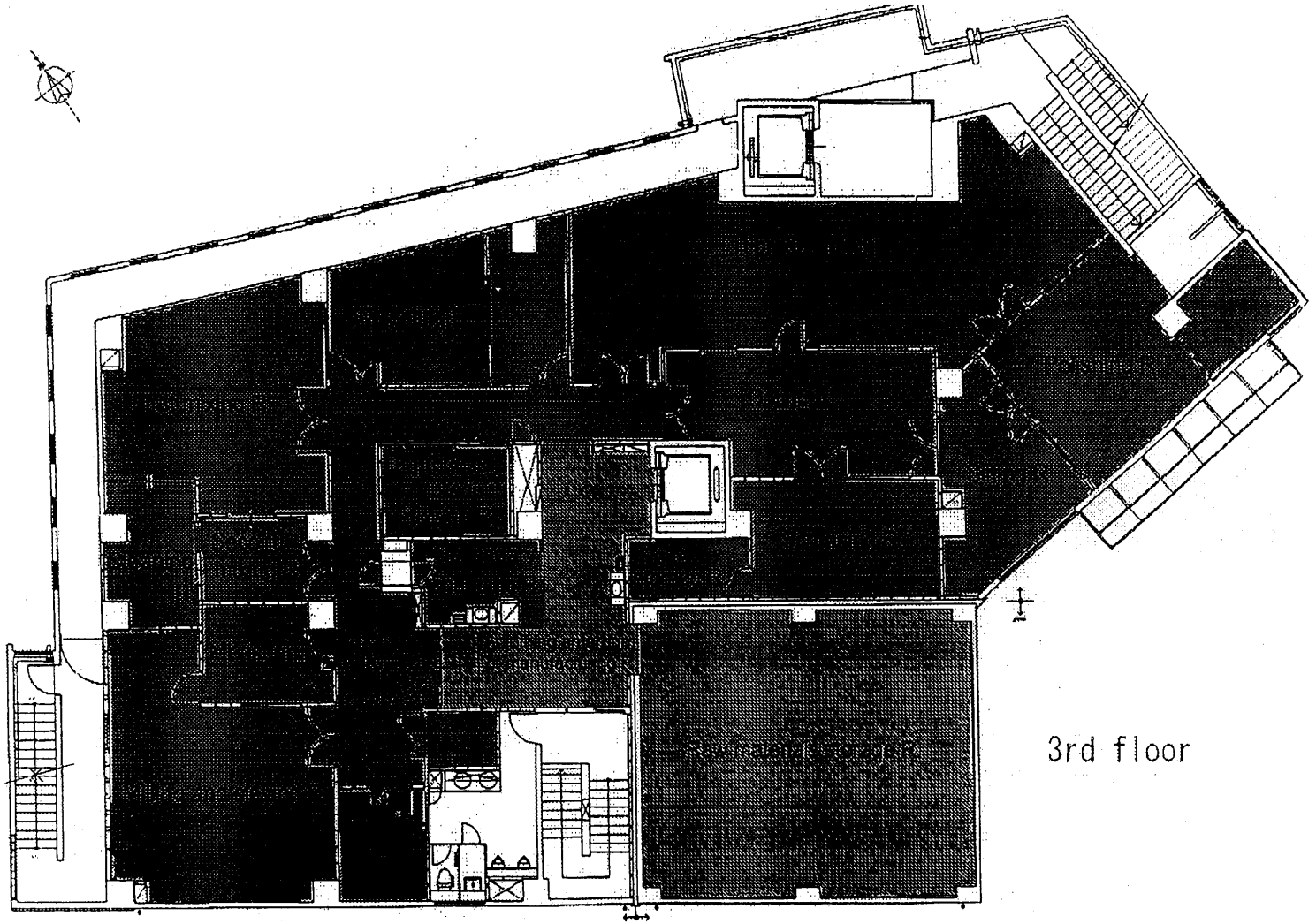
Basic concept of factory

① *Construction of facilities meeting the validation standard*

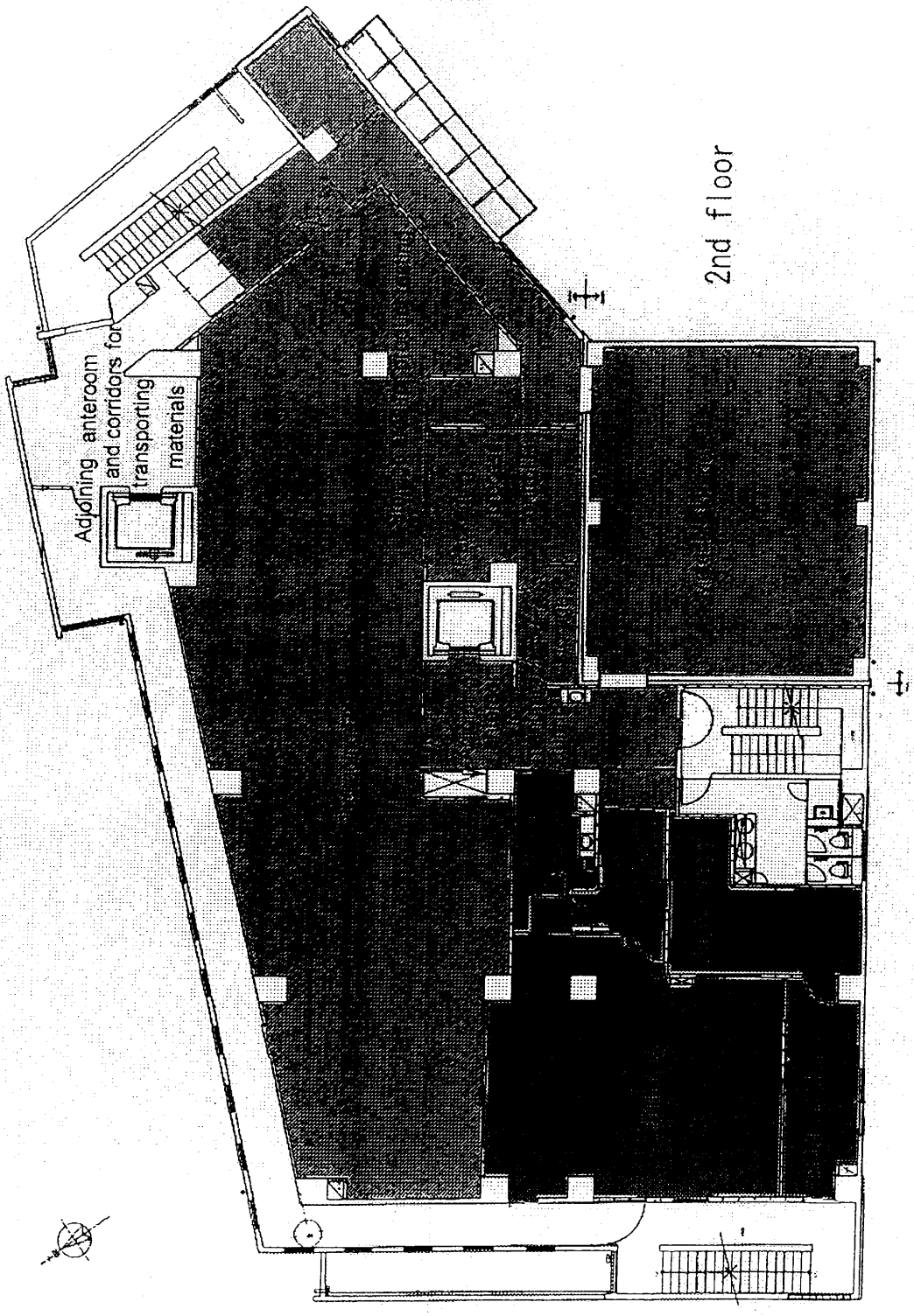
② *Securing an excellent manufacturing environment*

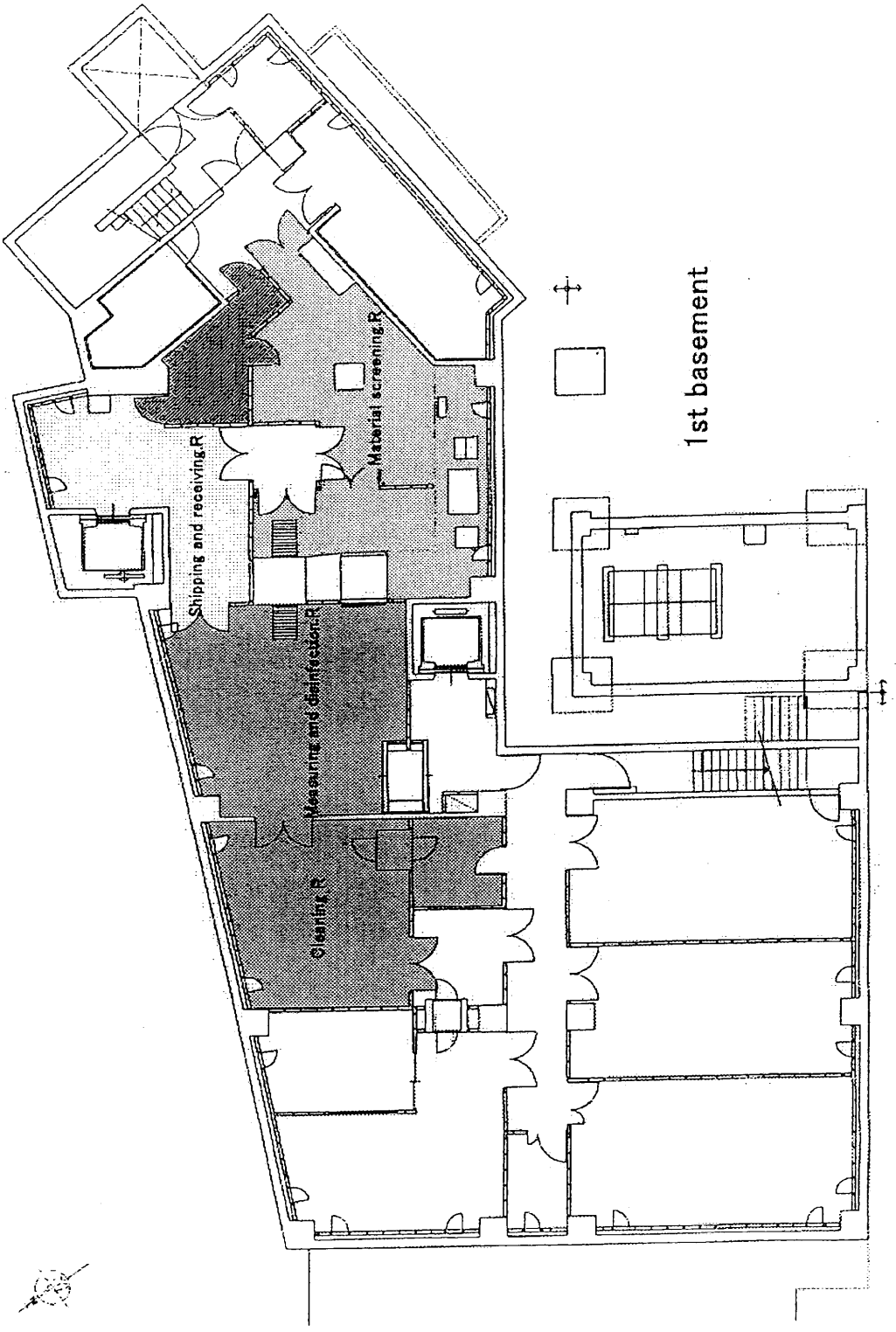
③ *Prevention of cross-contamination*

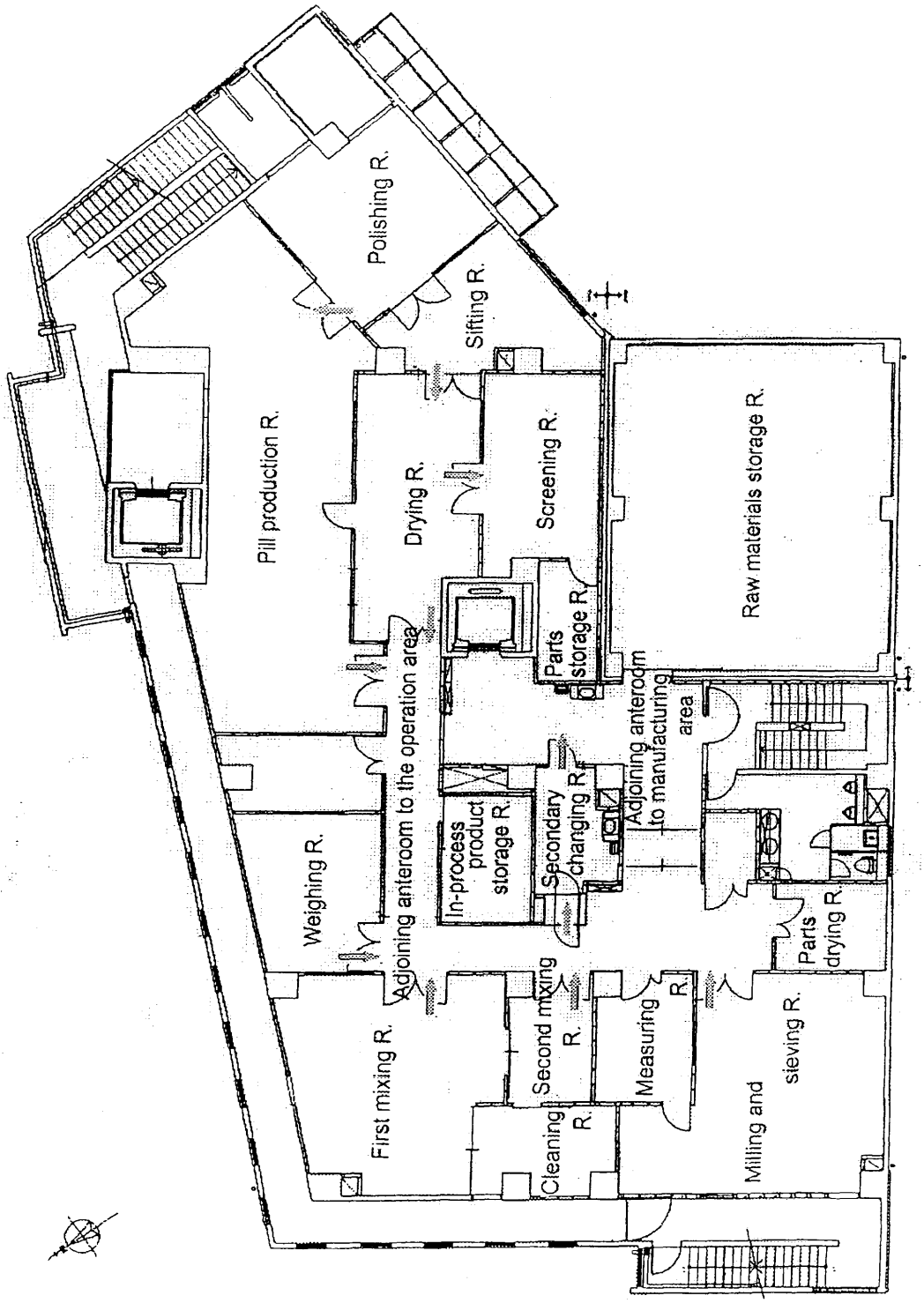
④ *Creating a working environment which is easy to work in*

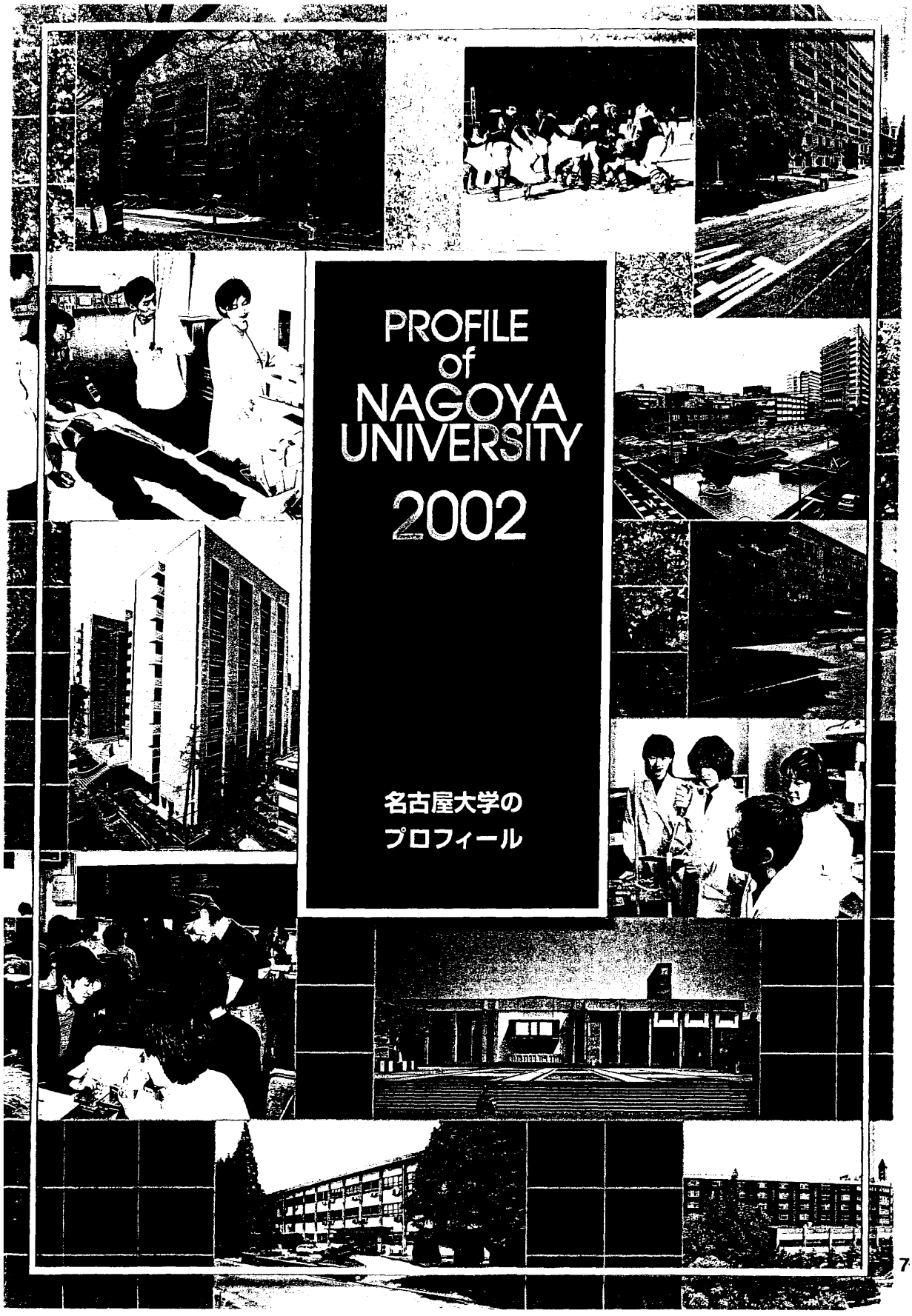


3rd floor


2nd floor
Adjoining anteroom and corridors for transporting materials


1st basement
Material screening R
Shipping and receiving R
Measuring and disinfection R
Clearing R


Polishing R.
Sifting R.
Pill production R.
Drying R.
Screening R.
Raw materials storage R.
Parts storage R.
Adjoining anteroom to the operation area
Adjoining anteroom to manufacturing area
Weighing R.
In-process product storage R.
Secondary changing R.
Parts drying R.
First mixing R.
Second mixing R.
Measuring R.
Cleaning R.
Milling and sieving R.


PROFILE
of
NAGOYA
UNIVERSITY
2002
名古屋大学の
プロフィール

名古屋大学学術憲章

名古屋大学は、学問の府として、大学固有の役割とその歴史的、社会的使命を確認し、その学術活動の基本理念をここに定める。

名古屋大学は、人間と社会と自然に関する研究と教育を通じて、人々の幸福に貢献することを、その使命とする。とりわけ、人間性と科学の調和的発展を目指し、人文科学、社会科学、自然科学をともに視野に入れた高度な研究と教育を実践する。このために、以下の基本目標および基本方針に基づく諸施策を実施し、基幹的総合大学としての責務を持続的に果たす。

1. 研究と教育の基本目標

(1) 名古屋大学は、創造的な研究活動によって真理を探究し、世界屈指の知的成果を産み出す。

(2) 名古屋大学は、自発性を重視する教育実践によって、論理的思考力と想像力に富んだ勇気ある知識人を育てる。

2. 社会的貢献の基本目標

(1) 名古屋大学は、先端的な学術研究と、国内外で指導的役割を果たしうる人材の養成とを通じて、人類の福祉と文化の発展ならびに世界の産業に貢献する。

(2) 名古屋大学は、その立地する地域社会の特性を生かし、多面的な学術研究活動を通じて地域の発展に貢献する。

(3) 名古屋大学は、国際的な学術連携および留学生教育を進め、世界とりわけアジア諸国との交流に貢献する。

3. 研究教育体制の基本方針

(1) 名古屋大学は、人文と社会と自然の諸現象を俯瞰的立場から研究し、現代の諸課題に応え、人間性に立脚した新しい価値観や知識体系を創出するための研究体制を整備し、充実させる。

(2) 名古屋大学は、世界の知的伝統の中で培われた知的資産を正しく継承し発展させる教育体制を整備し、高度で革新的な教育活動を推進する。

(3) 名古屋大学は、活発な情報発信と人的交流、および国内外の諸機関との連携によって学術文化の国際的拠点を形成する。

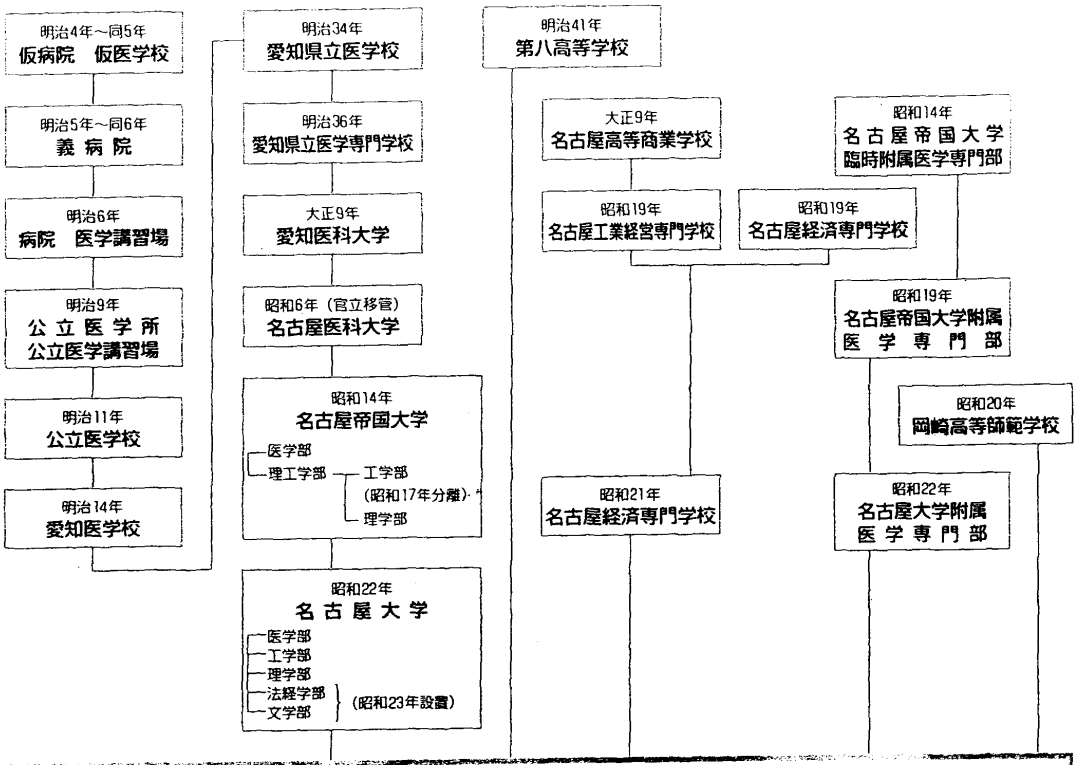
4. 大学運営の基本方針

(1) 名古屋大学は、構成員の自律性と自発性に基づく探究を常に支援し、学問研究の自由を保障する。

(2) 名古屋大学は、構成員が、研究と教育に関わる理念と目標および運営原則の策定や実現に、それぞれの立場から参画することを求める。

(3) 名古屋大学は、構成員の研究活動、教育実践ならびに管理運営に関して、主体的に点検と評価を進めるとともに、他者からの批判的評価を積極的に求め、開かれた大学を目指す。

大学の沿革



名古屋大学　昭和24年（新制）

文学部
教育学部
法経学部 ― 法学部 / 経済学部 （昭和25年分離）
情報文化学部（平成5年設置）
理学部
医学部
工学部
農学部（昭和26年設置）
分　校－教養部（昭和38年設置）－（平成5年廃止）
文学研究科
教育学研究科 － 教育発達科学研究科（平成12年名称変更）
法学研究科
経済学研究科
理学研究科
工学研究科
（昭和28年設置）
医学研究科 － 医学系研究科（平成14年名称変更）
農学研究科 － 生命農学研究科（平成9年名称変更）
（昭和30年設置）
国際開発研究科（平成3年設置）
人間情報学研究科（平成4年設置）
多元数理科学研究科（平成7年設置）
国際言語文化研究科（平成10年設置）
環境学研究科（平成13年設置）

昭和21年
環境医学研究所（大学附置）

昭和24年　平成2年
空電研究所（大学附置）－ 太陽地球環境研究所（大学附置・全国共同利用）

昭和18年　昭和20年
航空医学研究所（大学附置）－廃止

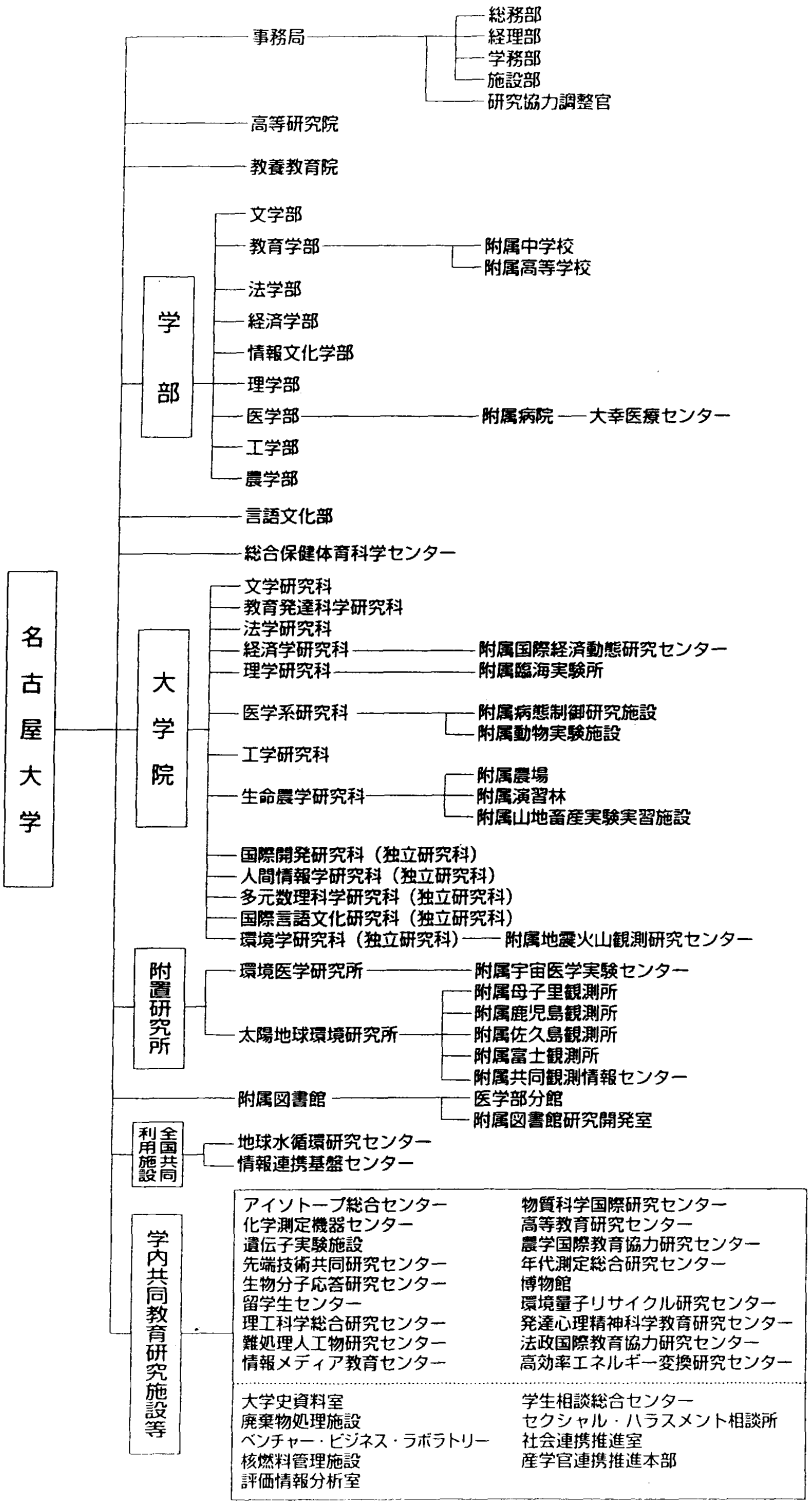
昭和36年　平成元年
プラズマ研究所（大学附置）－ 核融合科学研究所（大学共同利用機関）へ発展

昭和48年　平成5年
水圏科学研究所（大学附置）－ 大気水圏科学研究所（大学附置・全国共同利用）－（平成13年廃止）

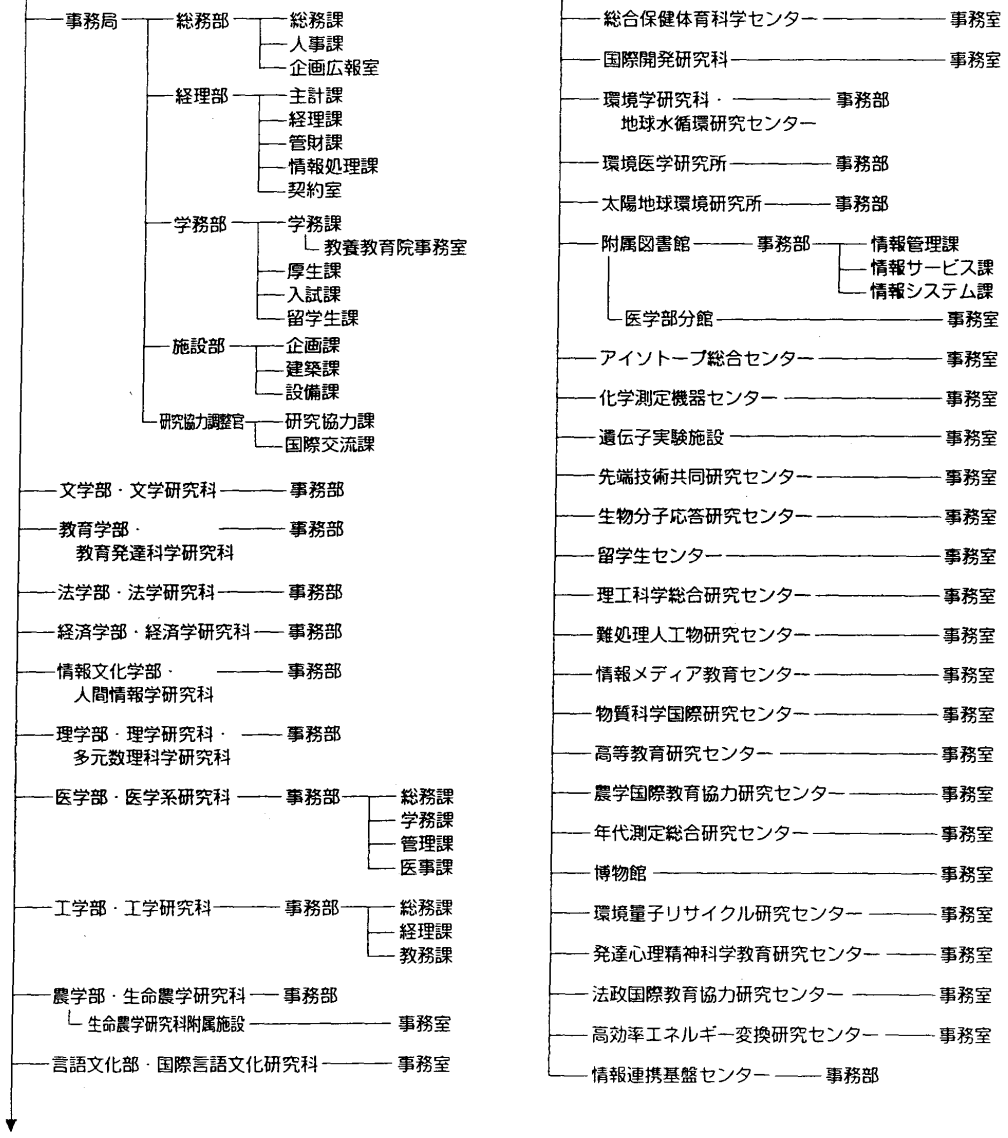
昭和52年
名古屋大学医療技術短期大学部（名古屋大学併設）－（平成13年廃止）

大学の組織・機構

組織図


名古屋大学
事務局
総務部
経理部
学務部
施設部
研究協力調整官
高等研究院
教養教育院
学部
文学部
教育学部
附属中学校
附属高等学校
法学部
経済学部
情報文化学部
理学部
医学部
附属病院
大幸医療センター
工学部
農学部
言語文化部
総合保健体育科学センター
大学院
文学研究科
教育発達科学研究科
法学研究科
経済学研究科
附属国際経済動態研究センター
理学研究科
附属臨海実験所
医学系研究科
附属病態制御研究施設
附属動物実験施設
工学研究科
生命農学研究科
附属農場
附属演習林
附属山地畜産実験実習施設
国際開発研究科（独立研究科）
人間情報学研究科（独立研究科）
多元数理科学研究科（独立研究科）
国際言語文化研究科（独立研究科）
環境学研究科（独立研究科）
附属地震火山観測研究センター
附置研究所
環境医学研究所
附属宇宙医学実験センター
太陽地球環境研究所
附属母子里観測所
附属鹿児島観測所
附属佐久島観測所
附属富士観測所
附属共同観測情報センター
附属図書館
医学部分館
附属図書館研究開発室
全国共同利用施設
地球水循環研究センター
情報連携基盤センター
学内共同教育研究施設等
アイソトープ総合センター
化学測定機器センター
遺伝子実験施設
先端技術共同研究センター
生物分子応答研究センター
留学生センター
理工科学総合研究センター
難処理人工物研究センター
情報メディア教育センター
物質科学国際研究センター
高等教育研究センター
農学国際教育協力研究センター
年代測定総合研究センター
博物館
環境量子リサイクル研究センター
発達心理精神科学教育研究センター
法政国際教育協力研究センター
高効率エネルギー変換研究センター
大学史資料室
廃棄物処理施設
ベンチャー・ビジネス・ラボラトリー
核燃料管理施設
評価情報分析室
学生相談総合センター
セクシャル・ハラスメント相談所
社会連携推進室
産学官連携推進本部

事務機構図


事務局
総務部
総務課
人事課
企画広報室
経理部
主計課
経理課
管財課
情報処理課
契約室
学務部
学務課
教養教育院事務室
厚生課
入試課
留学生課
施設部
企画課
建築課
設備課
研究協力調整官
研究協力課
国際交流課
文学部・文学研究科 事務部
教育学部・教育発達科学研究科 事務部
法学部・法学研究科 事務部
経済学部・経済学研究科 事務部
情報文化学部・人間情報学研究科 事務部
理学部・理学研究科・多元数理科学研究科 事務部
医学部・医学系研究科 事務部
総務課
学務課
管理課
医事課
工学部・工学研究科 事務部
総務課
経理課
教務課
農学部・生命農学研究科 事務部
生命農学研究科附属施設 事務室
言語文化部・国際言語文化研究科 事務室
総合保健体育科学センター 事務室
国際開発研究科 事務室
環境学研究科・地球水循環研究センター 事務部
環境医学研究所 事務部
太陽地球環境研究所 事務部
附属図書館 事務部
情報管理課
情報サービス課
情報システム課
医学部分館 事務室
アイソトープ総合センター 事務室
化学測定機器センター 事務室
遺伝子実験施設 事務室
先端技術共同研究センター 事務室
生物分子応答研究センター 事務室
留学生センター 事務室
理工科学総合研究センター 事務室
難処理人工物研究センター 事務室
情報メディア教育センター 事務室
物質科学国際研究センター 事務室
高等教育研究センター 事務室
農学国際教育協力研究センター 事務室
年代測定総合研究センター 事務室
博物館 事務室
環境量子リサイクル研究センター 事務室
発達心理精神科学教育研究センター 事務室
法政国際教育協力研究センター 事務室
高効率エネルギー変換研究センター 事務室
情報連携基盤センター 事務部

歴代総長・運営諮問会議委員

歴代総長

		就任	退任
初代総長	渋沢　元治	[redacted]	昭和21.1.31
2代総長	田村　春吉	[redacted]	昭和24.5.17
（事務取扱）	生源寺　順	[redacted]	昭和24.7.11
3代総長	勝沼　精蔵	[redacted]	昭和34.7.10
4代総長	松坂　佐一	[redacted]	昭和38.7.10
5代学長	篠原　卯吉	[redacted]	昭和44.5.20
（事務取扱）	芦田　淳	[redacted]	昭和44.7.22

		就任	退任
6代学長	芦田　淳	[redacted]	昭和50.7.21
7代学長	石塚　直隆	[redacted]	昭和56.7.21
8代学長	飯島　宗一	[redacted]	昭和62.7.21
9代学長	早川　幸男	[redacted]	平成 4.2. 5
（事務取扱）	松尾　稔	[redacted]	平成 4.4. 1
10代総長	加藤　延夫	[redacted]	平成10.3.31
11代総長	松尾　稔	[redacted]	

運営諮問会議委員

氏　名	役　職
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岡　崎　恒　子	藤田保健衛生大学総合医科学研究所教授
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（五十音順）

運営諮問会議

平成14年5月1日発行　第53巻第6号（年6回発行）　昭和57年7月学術刊行物指定　ISSN0287-4857

日本東洋医学雑誌

Japanese Journal of Oriental Medicine

第53巻第6号
2002年5月

第53回日本東洋医学会学術総会

会期
平成14年5月31日（金）～6月2日（日）

会場
名古屋国際会議場

テーマ
大自然の恵みを両手に―花開く伝統医学―

社団法人 日本東洋医学会

第53回日本東洋医学会学術総会

第53回日本東洋医学会学術総会
会頭　荻原　幸夫
（名城大学薬学部）

テ　ー　マ：大自然の恵みを両手に、花開く伝統医学

会　　期：平成14年（2002年）5月31日（金）～6月2日（日）

会　　場：名古屋国際会議場
〒456-0036　名古屋市熱田区熱田西町1番1号
（会館代表）TEL：052-683-7711　FAX：052-683-7777
（総会本部直通）TEL：052-682-4955　FAX：052-682-4956

総合受付	1号館1階	アトリウム
第1会場	1号館2階	センチュリーホール
第2会場	1号館4階	レセプションホール
第3会場	4号館1階	白鳥ホール北
第4会場	4号館1階	白鳥ホール南
第5会場	1号館4階	141会議室
第6会場	1号館4階	142会議室
展示会場	1号館1階	イベントホール
総会本部	1号館3階	131・132会議室

事　務　局：〒464-8601　名古屋市千種区不老町
名古屋大学総合保健体育科学センター内
第53回日本東洋医学会学術総会事務局
準備委員長　佐藤　祐造
TEL：052-789-3962　FAX：052-789-3957

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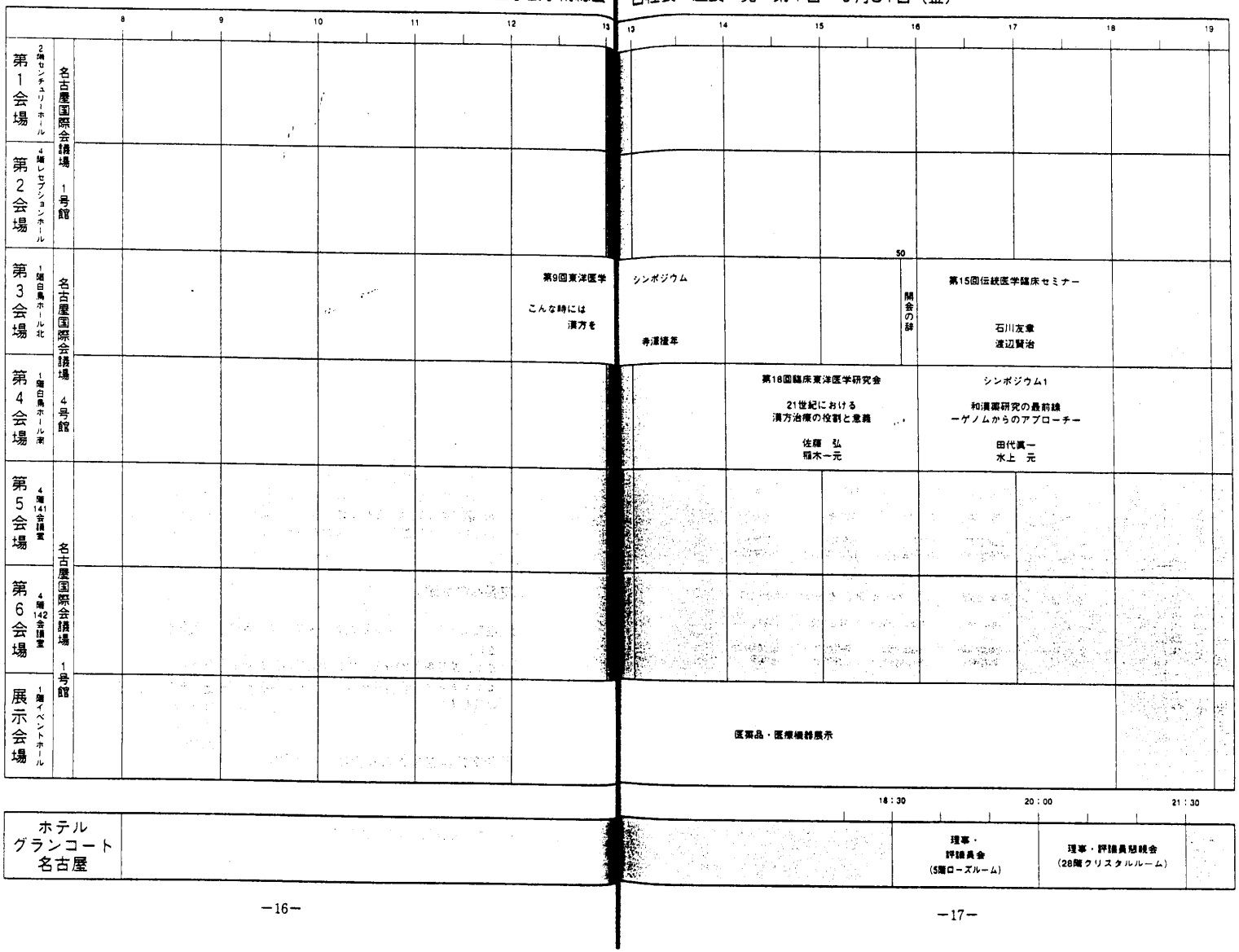
ご 挨 拶

第53回日本東洋医学会学術総会
会頭　荻原幸夫
（名城大学薬学部 教授）

東海支部、長年の懸案であった学術総会の開催が目前に迫って参りました。過去2年間、東海支部が一丸となって取り組み準備してきた日々が走馬灯のように脳裏をかすめ、よくここまできたとの思いで一杯です。昭和48年に高木健太郎先生のもと第24回の総会が名古屋で開催されてから、29年の年月が過ぎ去りました。私事ですが、この年の7月に名古屋市立大学に赴任、以来漢方処方の科学的評価研究に打ち込み、本年3月に定年退職する巡り合わせに感無量です。当時のプログラムによると、一般演題30、特別講演2、シンポジウム1とあります。その後、日本東洋医学会は先輩方のご努力により日本医学会加入に成功し、約一万人の会員を擁する学術団体へと成長、今回の学術総会のプログラムでは、各種講演10、受賞講演2、シンポジウム13、各種セミナー6および初心者向けの漢方入門セッションと非常に多岐にわたる盛り沢山の内容となりました。特に、シンポジウムは東海支部の役員の先生方全員が、それぞれの専門分野で企画・話題提供者選択にあたるとともに座長をしていただきます。なお、一般演題は238題と例年並ですが、鍼灸関連の31題とかなりの数が出揃いました。一般講演を含め5～6の企画が同時進行致します。参加者の皆様には、興味に応じて会場を選択していただき、活発な討論をお願い致したく思います。ご承知のように、1994年の米国議会による栄養補助食品法案の承認は、米国に代替医療ブームを招来し、FDAに代替医療局が設立され、年間5億ドルの予算がつき、伝統医学の見直しを本格的に開始しました。我が日本東洋医学会も石橋新会長直属のEBM特別委員会を発足させ、秋葉委員長のもと学会主導で漢方の現代科学化に本格的に取り組むことになりました。言うまでもなく、歴史的背景、東西文化の狭間、科学的研究能力等すべての面で、我が国は本課題に取り組み漢方を現代医療の場で正当に評価するに当たり、最も有利な立場にあると共にその義務があると考えており、学術総会は最も重要な舞台であります。本学術総会が所期の目的にかなうよう期待しております。

多数の先生のご参加を心からお待ちしております。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第1会場
2階センチュリーホール
第2会場
4階レセプションホール
名古屋国際会議場 1号館
第3会場
1階白鳥ホール北
第4会場
1階白鳥ホール南
名古屋国際会議場 4号館
第5会場
4階141会議室
第6会場
4階142会議室
名古屋国際会議場 1号館
展示会場
1階イベントホール
第9回東洋医学
こんな時には
漢方を
寺澤捷年
シンポジウム
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閉会の辞
第15回伝統医学臨床セミナー
石川友章
渡辺賢治
第18回臨床東洋医学研究会
21世紀における
漢方治療の役割と意義
佐藤　弘
稲木一元
シンポジウム1
和漢薬研究の最前線
ーゲノムからのアプローチー
田代眞一
水上　元
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20：00
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グランコート
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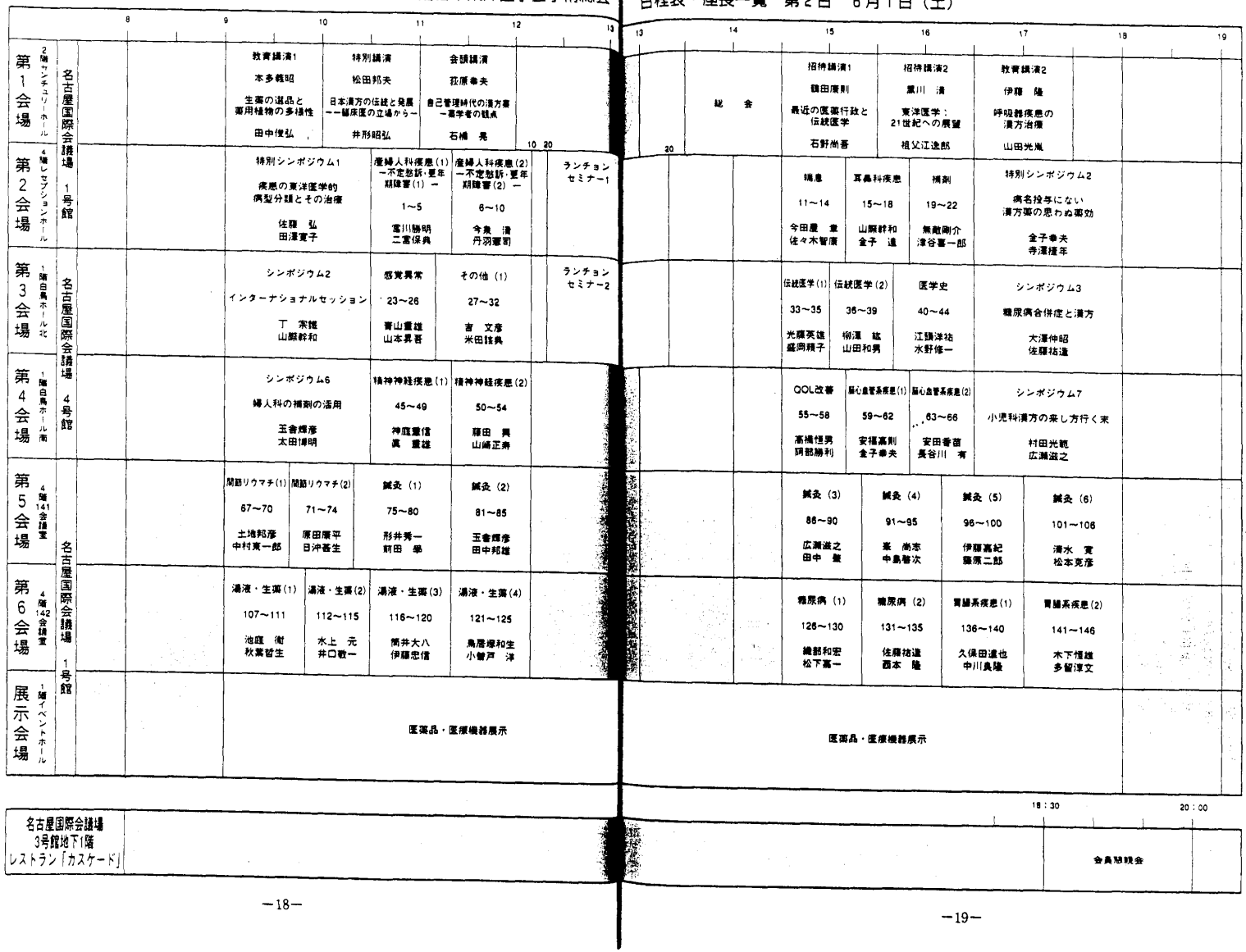
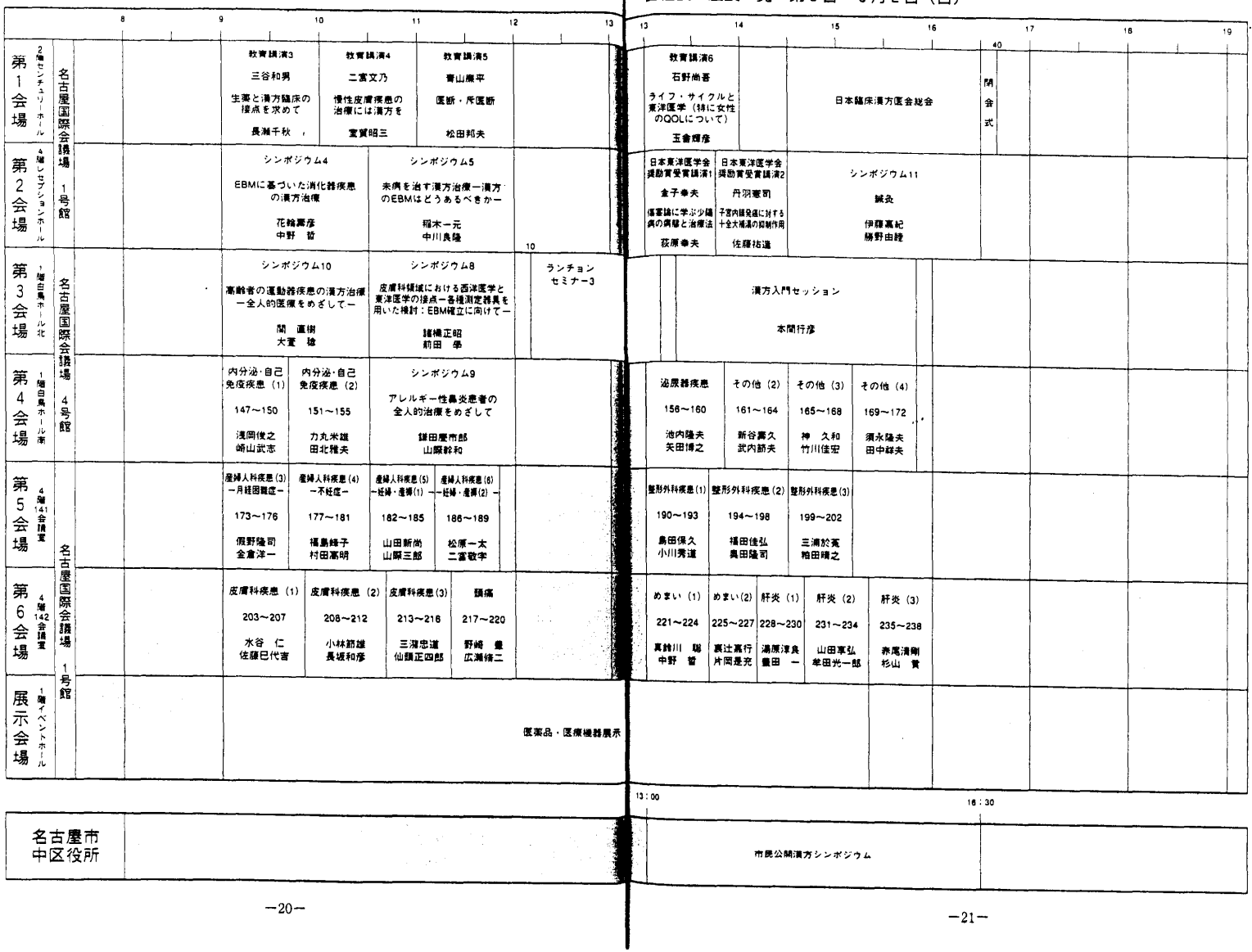
理事・
評議員会
（5階ローズルーム）
理事・評議員懇親会
（28階クリスタルルーム）

第53回日本東洋医学会学術総会

日程表・座長一覧　第2日　6月1日（土）

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13：00
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名古屋市中区役所
市民公開漢方シンポジウム