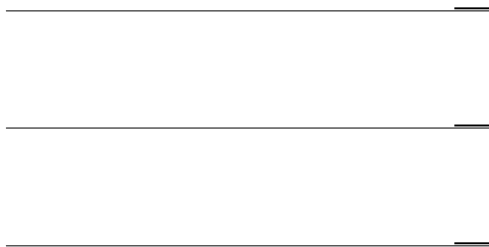


2002 2



2

가

가

가

가

가

[]

“

...”

1	-----	1
1.1.	-----	1
1.2.	-----	2
2	-----	4
2.1.	-----	4
2.2.	-----	4
3	-----	6
3.1.	-----	6
3.1.1.	-----	6
3.1.2.	가 -----	13
3.1.3.	-----	19
3.1.4.	-----	22
3.2.	가 -----	24
3.2.1.	-----	24
3.2.2.	-----	29
3.2.3.	-----	33
3.2.4.	-----	39
3.2.5.	GHTF -----	43
4	-----	50
4.1.	-----	50

4.2.		-----	52
4.3.	가	-----	53
4.4.		-----	63
4.5.		-----	63
5		-----	67
6		-----	69
		-----	71
		-----	73

1.				-----	7
2.			.	-----	8
3.				-----	9
4.				-----	10
5.				-----	11
6.				-----	12
7.				-----	13
8.	가			-----	14
9.				-----	15
10.				-----	16
11.				-----	17
12.				-----	19
13.				-----	21
14.				-----	25
15.				-----	30
16.				-----	36
17.				-----	40
18.	GHTF	가		-----	48
19.	가			-----	53
20.	가			-----	55
21.	가			-----	56
22.	가	가	가	-----	58
23.	가			-----	60
24.	가			-----	62

1	-----	5
2	(1) -----	26
3	가(2, 3) -----	27
4	-----	31
5	-----	37
6	-----	41

가

가

가

2000 1 2,665 9,202

가 (609)가 (644)

70% 20

가

2000 250 2004 294

21 가가

(WTO)

(GHTF)

가

,

, , ,

.

, , ,

가

,

, 가 ,

가

,

, 가, ,

,

,

.

1

1.1.

가 1989 4,200 가 2000 4,700
1993
1 7,523 2000 4 1,400 가 (
가 , 2000).
1970 가
1998 41 가 3,300 19
(, 1999). 1975
37 11,188 , 1998 255
34,587 가 .(, 1999). 1977
가
가 가
가
2000) 가
가 .

가

가

가 .

1991 4,234 2000 1 2,665

(, 2001)

가 (, 1998).

가

가

가

1.2.

, , 가

가

가 가

GHTF(Global Harmonization Task Force)

가

가

가 ,

가

가

2

2.1.

가 가
가

가

가

(WTO)

(GHFT; Global Harmonization Task Force)

(ISO; International Standard

Organization) GHTF

2.2.

가

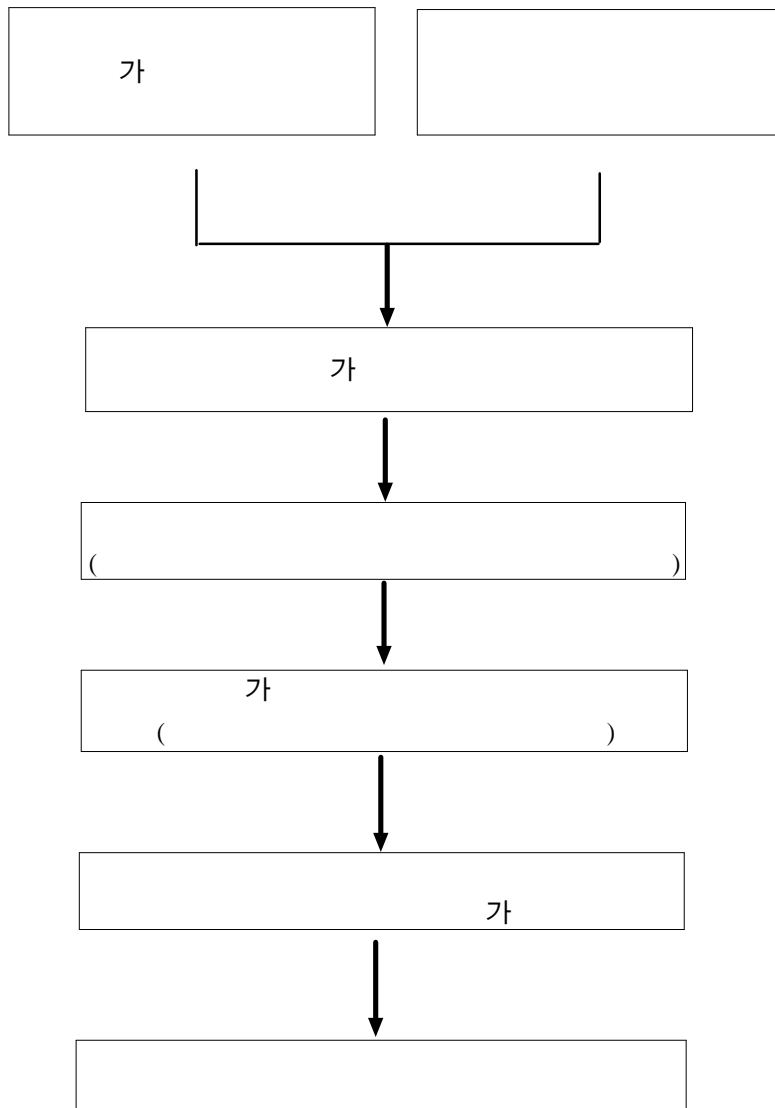
가가

가

가

가 가

가 .



(1)

3

3.1

3.1.1.

가.

1960
가
1970
가, 1980
1990
가가
(1).
1980
가
가가
가 1990 144 1997 221 , 2000 236 , 2001 248 ,
2002 261 , 2005 349
6% (, 1998 ; ,
2002).

(1)

1960	,	,		
1970	,			
1980	,	,	,	,
1990	2001	,	,	

: , 2000 ; , 2001

(X) X- , ,
, 가 407
가 50 가 (, 1997).

1) .

가 2000 1991 408
236 2000 609 가 가 가 1991
644 가 가 가 (2).
1991 2000 295 가 가 408
가 가 가 .
1991 3,443 1995 4,252 2000
6,276 .

(2)

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
	314	340	324	365	400	401	407	411	477	609
()	(3,443)	(3,685)	(3,669)	(3,930)	(4,253)	(4,348)	(4,140)	(4,183)	(4,373)	(6,276)
	236	104	273	316	399	518	728	823	560	644

: , 2001 ; , 2001

2)

1991 4,274 1993 5,038
 5,000 1,000 1999 1
 477 1 2000 1 2,665
 IMF 1998 6,647 1997 2,000
 가 .
 1991 1,170
 1995 1,611 , 1998 3,607 , 2000 3,463
 1991 3,064 , 1995 5,749 , 1999 6,870 , 2000 9,202
 가 가 3 가 .
 1991 2,140
 1995 2,894 , 1999 6,870 , 2000 7,701 10 4 가
 2005 1 2,000 (33% 가)
 2010 2 6,000 (23%) 가 (, 2001).
 1991 970 , 1995 1,283 , 1999 3,263 ,
 2000 5,238 1991 45% 2000 60%

가 (3).

(3)

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000
	4,234	4,494	5,038	6,579	7,360	8,425	8,758	6,647	10,477	12,665
()	1,170	1,531	1,550	1,462	1,611	1,730	2,035	1,322	3,607	3,463
	3,064	2,963	3,488	5,117	5,749	6,695	6,723	5,325	6,870	9,202
	2,140	2,400	2,530	2,639	2,894	3,348	4,011	4,334	6,870	7,701
	970	869	980	1,177	1,283	1,618	1,976	3,012	3,263	5,238

: , 2001 ; , 2001

3)

2000

7,901

30% , , 가 , 가 , 1997 149 , 2000 1,069 3 7 가 . 19% 1988 , 1999 59% , 68% , 1988 , 59%

(4)

:

	1997	1998	1999	2000
	810	843	2,204	1,950
.	289	394	439	537
	91	69	57	-
	50	79	107	60
	386	353	511	-
.	675	797	874	-
	237	284	274	-
	431	454	673	-
	530	605	788	-
	126	110	210	-
	229	193	473	-
가	149	149	256	1,069
	4,011	4,334	6,870	7,701

: , 2001

가 가 , , , , ,
 , , , , 가
 가가 .
 1997 7,571 IMF 1998 4,427
 가 1999 6,058 2000 9,113
 가 (5).

(5)

:

	1997	1998	1999	2000		
	358	145	238	302	,	,
	150	54	96	155	,	,
	338	130	216	425	,	,
	253	104	201	281	,	
	259	239	246	374	,	,
	456	86	146	272	,	,
	224	290	156	212	,	,
	119	103	103	-		,
	124	6	118	-	,	,
	49	19	30	-	,	,
	5,273	3,187	4,502	7,088		-
	7,571	4,427	6,058	9,113		

:

, 2001

, , , , , , ,

, , , ,

, , , , ,

1996 4,361

가

1999 1 951

(6).

(6)

:

	1996	1997	1998	1999	
	1,638	1,651	327	453	,
	1,303	1,256	1,297	1,225	,
	178	122	110	113	,
	682	609	630	899	,
	4,361	6,307	7,481	10,951	,
	2,698	3,172	3,544	3,608	,
.	656	711	597	737	,
	460	621	800	4425	,
	377	798	584	347	,
	246	232	355	359	,
	6,572	6,772	9,310	9,615	-
	191	222	250	287	-

: , 2001

4)

1998 300 가 3 , 200 300 6 , 200 100
 16 6.1 , 50 가 75% 2000
 300 1 , 200 300 11 , 100 200 15 4.5% , 50
 가 68.8% . 50 가 68%

(7).

() 2000

100 14 2% 100 50 13
 , 50 10 108 , 10 1 205 , 1 142 .

(7)

: , %, ,%

		1998				1999				2000			
300	3	0.7	1,615	14.3	5	1.0	2,094	14.3	1	0.2	430	3.0	
200	300	6	1.5	1,447	12.8	4	0.8	975	12.8	11	1.8	2,739	19.4
100	200	16	3.9	2,388	21.1	17	3.6	2,555	21.1	15	2.5	2,264	16.0
50	100	24	5.8	1,593	14.1	29	6.1	2,014	14.1	37	6.1	2,588	18.3
20	50	76	18.5	2,344	20.8	86	18.0	2,633	20.8	104	17.1	3,236	22.8
20		233	56.7	1,909	16.9	255	53.3	2,195	16.9	315	51.7	2,906	20.5
		411	100	11,296	100	478	100	12,466	100	609	100	14,163	100
		53	12.9	-	-	82	17.2	-	-	126	20.6	-	-

: , 2001

3.1.2. 가

1995 1,199 1990 2000 2005 5-6% (6.6%) (6.4%)
 7% (,
 2000).
 , ,
 2000 17%, 2005 25%
 2050 50%
 (, 98). 2020
 가가 , 2025
 (HIMA Energy Market's report, 1999).

가 10%

20%

(8).

(8) 가

:

	1998	1999	2000	2001	2002	2003	2004
	10,557	11,559	12,368	12,863	13,120	13,514	14,054
(, ,)	4,987	5,351	5,719	6,003	6,276	6,537	6,793
	3,163	3,573	3,681	3,828	4,019	4,220	4,389
(, 가 ,)	977	1,095	1,242	1,392	1,480	1,582	1,684
(, ,)	1,721	1,789	1,991	2,143	2,276	2,414	2,550
()	21,405	23,367	25,001	26,229	27,171	28,267	29,470

: Yearbook of World Electronics Data, 2001 ; , 2001

가 가

28.0%

(26.1%),

가

(,)

1998).

가가

1990 144

1995

198 , 1999 222 , 2000 236 , 2001 248 , 2005 349

6.1%

1999 63

2000

64 1.4%

1999 28

2000

32

13% . 2003
 4.8% 15% 7.7%
 (, 2001).
 가
 가 가
 44% , 21% , 20%
 1.7% (9).

(9)

: , %

	1997	1998	1999	2000	2001	2002	2003	가	
								99/00	00/03
	6,614	6,310	6,383	6,475	6,579	6,680	6,777	1.4	1.5
	3,324	3,042	3,255	3,372	3,646	3,851	4,044	4.0	6.2
E.C.G	217	224	237	253	267	278	288	6.7	4.4
	748	828	848	862	874	880	883	1.6	0.7
	6,070	6,624	7,269	8,043	8,693	9,403	10,080	10.6	7.7
	207	186	188	172	197	202	207	- 8.5	6.4
	2,275	2,592	2,846	3,216	3,319	3,529	3,702	13	4.8
	1,067	1,152	1,202	1,236	1,266	1,279	1,275	2.8	1.0
	20,522	20,958	22,228	23,629	24,841	26,102	27,256	5.7	4.8

: Yearbook of World Electronics Data, 2001 ;

, 2001

가.

2000 가 250 가 123
 가 2003 140
 (10).

(10)

:

1997	1998	1999	2000	2001	2002	2003
1,639	1,607	1,477	1,338	1,207	1,075	944
2,275	2,592	2,846	3,080	3,319	3,529	3,702
1,067	1,152	1,202	1,236	1,266	1,279	1,275
160	167	182	196	209	221	230
3,935	4,470	5,040	5,602	6,198	6,767	7,291
458	508	502	489	474	454	428
9,660	10,634	11,378	12,061	12,785	13,424	13,961

: Yearbook of World Electronics Data, 2001 ; , 2001

250 가 45% 가 가 40% 가
 . 50% 가 , 15%
 , MRI, CT .
 (DHHS)가
 (NIH : National Institutes of Health)가,
 (AdvaMed : Medical Technology
 Association)가 .
 18 6

, ISO
(, 2001).

2000 33
1997 38 2000 32 2003 38
(11).

(11)

	1997	1998	1999	2000	2001	2002	2003
	1,107	883	835	846	864	883	893
	149	130	132	136	141	146	150
	2,512	2,086	2,171	2,282	2,420	2,566	2,695
	83	76	81	87	94	101	108
	3,893	3,163	3,258	3,388	3,557	3,735	3,885

: Yearbook of World Electronics Data, 2001 ; , 2001

가

1999

() (,
 , GMP) GMP ,
 , , ,
 (, 2001).

57
 1997 44 2000 50 가 2003 60
 (12).

(12)

:

	1997	1998	1999	2000	2001	2002	2003
	128	144	149	155	163	170	178
	138	150	157	163	170	175	182
	93	105	109	115	121	126	131
	57	61	66	70	74	78	84
	787	824	866	909	945	961	1,062
	693	814	863	906	933	961	1,000
	54	62	72	82	95	104	109
	53	56	61	66	69	73	76
	632	648	661	694	715	743	773
	521	542	575	615	652	678	705
	84	95	100	104	108	111	115
	68	71	78	85	90	94	99
	208	264	285	305	317	333	343
	142	151	158	174	183	192	200
	231	234	241	250	258	268	282
	564	600	624	649	675	695	282
	4,454	4,821	5,065	5,344	5,568	5,805	6,063

: Yearbook of World Electronics Data, 2001 ;

, 2001

3.1.3.

가

(, 1998).

가 ,

, 가

G7 가

가

(, 1998).

()

, , GMP

가.

1979

가

,

가 1988 ,

가 1989 ,

가 1991 ,

가 1996 ,

1996 ,

1994 ,

1996

8

150 ,

80 ,

120 ,

80 ,

50 ,

50 ,

120 ,

120

770

(13).

.
가 가
가 .
가
(, 1998).
가 (, 2000)
가
가
가
가
(, 2000).
가 .
가 .
가 .

3.2. 가

3.2.1.

가.

가
(, 2001).
2001 7 1
2001 5
2 9 「 , , ,
(, 2001).
(, 2001).
2000
가
가
(,
2001).

3 (938)
 (91)
 (95-4)
 HS (harmonized commodity
 description and coding system)

. 1
 , 2 , , ,
 , 가 , 3
 . 가 ,
 (, 2001).
 1 (가) 2
 가 (,)
 . 3 가 , ,
 . (14).

(14)

		()
1	, 가	313
2	가 . ,	473
3	, 가 . ,	152
: , 1998 ; , 2001 ; , 2001		

. 가

가 () 가 () 가,
가 26 1 22

가

가

4

가 가

가 26 6 23

가 1 , 2, 3 가

8

가

가 (

2, 3).

()



()

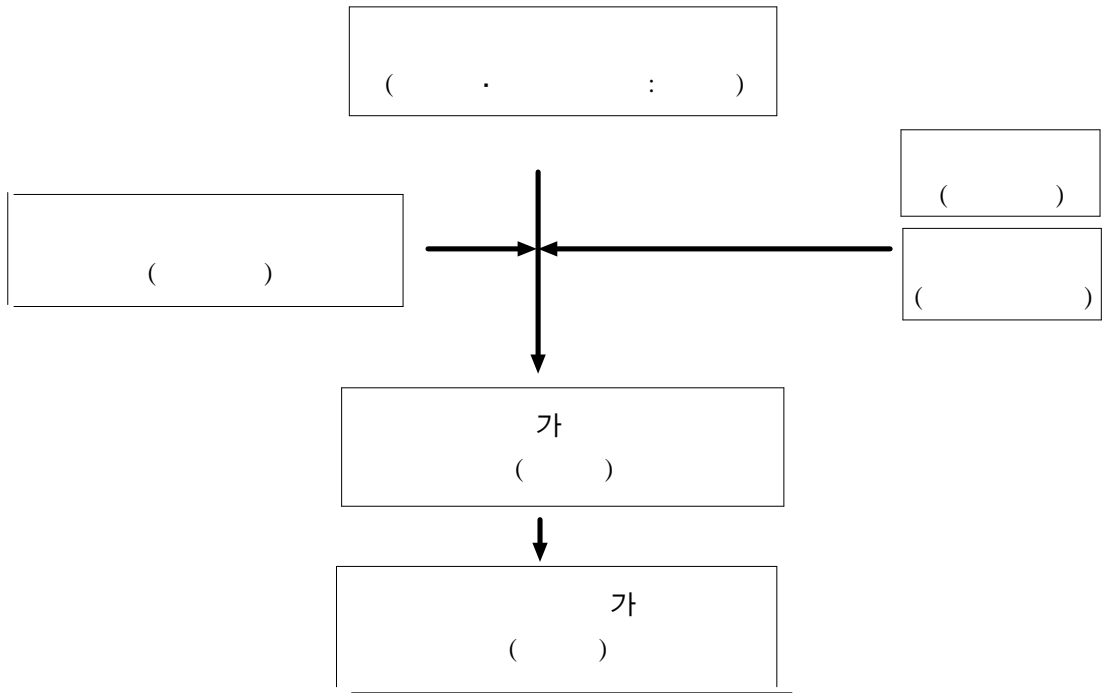


가
()

: , 2001

(2)

(1)



: , 2001
 (3) 가 (2, 3)

. 가

1997 7 1

2

()

() ,

(GMP;

Good Manufacturing Practice

)

.

,

4

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가

(2, 3

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GMP

1, 2, 3

,

가 . 가 가
GMP 가 .

가 , , 8 . ,
(
, 2001).

가 . 가
' 가 ,

가 .
, 200 () ,
()

가 .

(, 2001)

3.2.2.

가.

1938 (The Federal Food and Drug and Cosmetic Act) 1976 FDC Act Medical Device Amendments, 1990 Safe Medical Device Act, 1997 The Food and Drug Administration Modernization Act .

1997 FDA (, 1998).

(1938)

가

, 1995).

FDA 1976

GRAND FATHERING

가 , , GMP

1997 FDA 가 (, 2002).
 3
 가

1 가
 가 2
 , (510K), GMP . 3
 ,
 (PMA), GMP (15).

(15)

()

1	,	489
2	, FDA (510(K)), GMP	744
3	, (PMA), GMP	751

: , 1995 ; , 1998

. 가

FDC 510 , ,
 , , 가 FDA
 (, 1995)

, 가 FDA 3 7

2 (510(K)) 가

가 1 가 , 2

510(K) GMP , 3

(PMA) GMP , FDA가

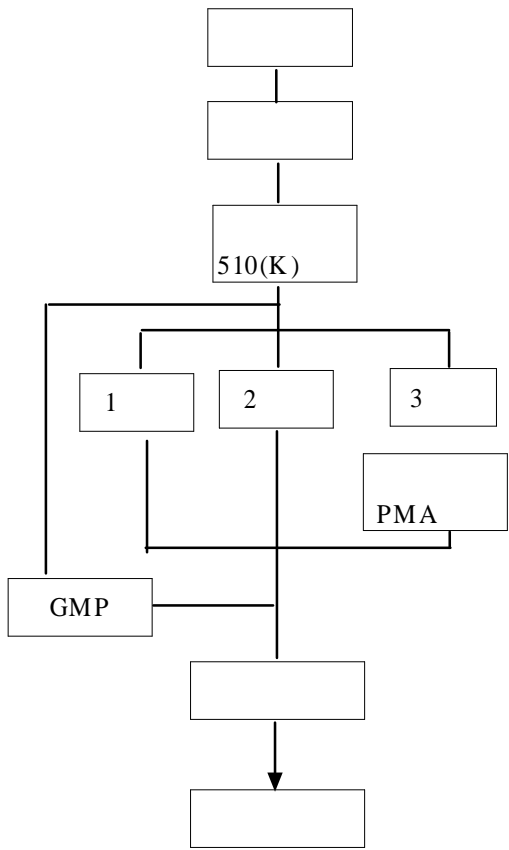
1 GMP

ISO9001 GMP

CGMP 2, 3 가 .

1 2 3

GMP (4).



: , 1995

(4)

, , GMP IDE ,
, , , FDA
가
가
,
. 가 ,
(510(K)) 2
, ,
, ,
, 90 275
(PMA) 3 ,
, ,
GMP 가 가 (, 2002).

1992 21 CFR part 821

가 가
,
(, 1995).
FDA
2, 3
가 36
3

. (PMA) FDA가
 가
 가 .
 FDA
 .
 가
 가
 ,
 1984 FDA
 FDC FDA

3.2.3.

가.

가
 CE
 EC 3가 .
 ,
 (Active Implantable Medical
 Devices Directive ; AIMD) .
 , ,
 (Medical Devices
 Directive ; MDD) ,
 , , , ,
 (In

Vitro Diagnostic Medical Device Directive ; IVD) (, 1995).
MDD 1998 6 14 ,
. AIMD 1995 1 1 ,
IVD ,

1998 1999 . EMC
AIMD, IVD MDD 가
1995
12 31 () 가 1996 1 1
가
, , 가 (, 1998).

「 , , , , , , ,
, , ,
, , ,
」
(. 1995).

가
.
, , , ,

가 가 , 가

가 , 가

4

CLASS I, IIa, IIb, III , 가

, CE

가 (, 1998) 가 () 4

가 (, 2001).

(16).

(16)

Class	,	,	,	,	가 ()
Class a	,	,	,	,	H, A C ()
Class b	X	,	,	,	H, B ()
Class	,	,	,	,	H, B ()

: , 1998 ; , 2002

. 가

Class 가 Class a
가
. Class b
,
, Class
(
, 1998). 1 Class a- b,
Class 가
가 .

가

가

A-H 8

가 (, 2002). A()

, B()

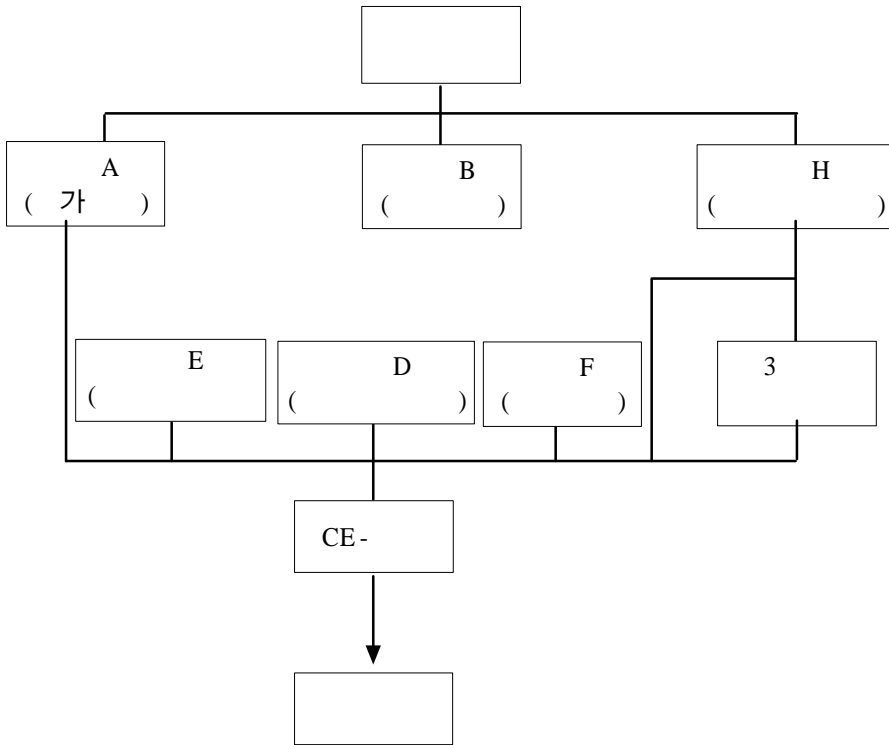
, D()

E()

F()

H()

(5).



: 1995

(5)

가 가 H
(NB; Notified Body) CE

가

(, 2002).

EC H CE
EC (NB) ()

H D 2 GMP

GMP

(, 1995).

EC 가 2

. CE 가

가 (, 1995).

가 (, 1998).

3.2.4.

가.

, , , . 1994
 ,
 ,
 (Global Hamonization Task Force,
 GHTF) (, 2001).

가 (, 1998).

.

「

,

. 政令 」 2 4 .

2 6

가

가

14

(, 1995).

.

1998 3

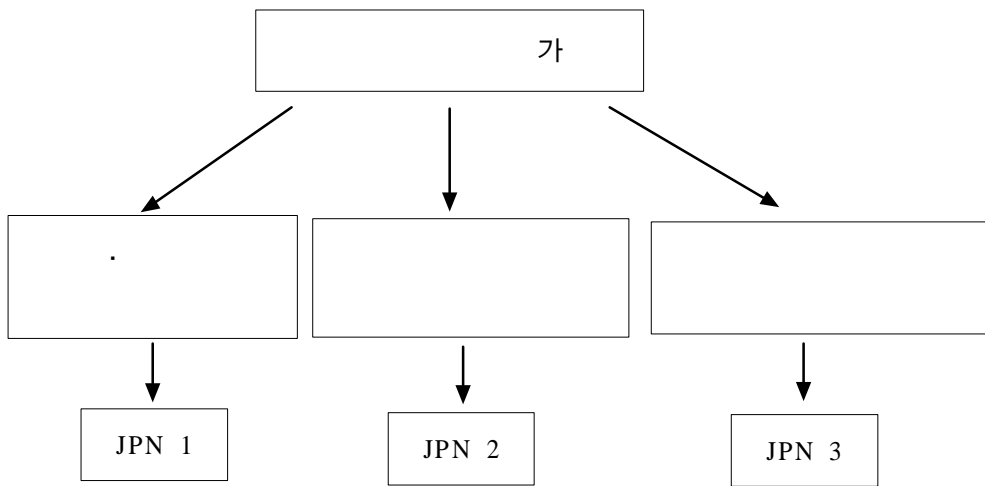
4

1 .
 2
 가 가
 3 가
 . 4
 , 가 가
 가 (17).
 (17)

1	.	,	,	284
2	.	,	, 가	- () 235
3	.	,	,	74
4	.	,	, ,	- - 13
: , 1998 ; , 2001				

JPN3 . 1 JPN1, JPN2,

2 1 가 , 3
 , 4
 가 (6).



: , 2001
 (6)

가

() 가 12 14
 가 19 2 가가 가
 가 12 3 5
 400 , 가

가

,

가

14

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가

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가

1

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2001).

3 4

가,

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2001).

가

1987

1988

3

GMP

가

1988

ISO9000

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EC EN46000

1994

QA

(GMP)

GMP

ISO 9000

1995

7

GMP

2, 3, 4

QA

1

ISO 9000, GMP, QA

1

가 ‘ ’ 3 GMP

가 GMP (, 2001).

, () JIS T 1001, 1002

GLP 가

가 가

3.2.5. GHTF (Global Harmonization Task Force,
)

GATT가 ,

125

가 UR 1995 (WTO)가 .

WTO

가

가

1993 1 , ,

GHTF가 .

·
(, 1995).

가. GHTF

1993 1 ,
(GHTF)가 ,
(,
1998).

· GHTF

GHTF

·
가
가

GHTF (Global Harmonization)
,
(, 1998).

· GHTF .

4 Study Group , Group

GFTF

Study Group 1 (Regulatory System)

(Technical File)

(Essential Principles of Safety & Performance of Medical Devices) 가
(Role of Standards in the Assessment of Medical Devices) .

Study Group 2 (Vigilance System)

가

(Manufacturer's Reporting Decision Tree)

(Comparison of the Devices Adverse Reporting System In USA, Europe, Canada, Australia & Japan)

가 (Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative) .

Study Group 3 (Quality System)

ISO 9000/ EN46000

GMP

(Software Validity)

(Process Validity)

(Auditor)

가 (Guidance on Quality System for the Design & Manufacturing of Medical Devices),

가 (Design Control Guidance for Medical Device Manufacturers), 가 (Process Validation Guidance for Medical Manufacturers) .

Study Group 4 (Quality Auditing Procedure)

(Auditor)

가

가 (Guidelines for
Regulatory Auditing of Quality System of Medical Device Manufacturers- Part
I: General Requirements), (Audit Language Requirements for
Auditors) (, 1998).

. GHTF

GHTF Study Group 1

,

가

가

가

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(

가

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가 ,

(
) ,

가

, 가 가

(moving parts)

가
가

가

가

가

가

(, 1998).

. GHTF 가 (18)

(18) GHTF 가

가	
	FDA Food and Drug Administration
	MDB Medical Devices Bureau/Health Canada
	Department of Control de insumos para la salud
	HIMA Health Industry Manufacturers Association
	NEMA National Electrical Manufacturer's Association
	MEDEC Medical Economics Company
EU	EU European Commission
EU	EFTA European family Therapy Association
EU	EDMA European Diagnostic Manufacturers Association
EU	EUCOME European Confederation of Medical Devices' D Association
EU	COCIR
EU	IAPM International Association of Medical Prothesis Manufacturers
	MHW Ministry of Health and Welfare
	TGA Therapeutic Goods Administration
	JFMDA Japan Federation of Medical Devices Association
	MIAA Medical Industry Association of Austrailia
Observ ers	ISO, W.H.O, ARGENTINA, BRAZIL, CUBA, CZECH REP. HUNGARY, INDIA, INDONESIA, ISRAEL, KOREA, MALAYSIA, CHINA,POLAND,SINGPORE THAILAND

: , 1998

. GHTF (ISO; International Standard Organization)

‘ ’ ISO 13485 ISO 210 .
ISO ‘ ’ ISO 176 , ‘ ’ ISO 202 , ‘
, 178 가 .
ISO 210 , ,
(observer member) .
ISO 210 (, , ,
)
ISO ,

GHTF . GHTF
, , , 5 . GHTF ISO/TC
210 99 MOU(Memorandum of Understanding.)

가

, GHTF

ISO/TC 210

ISO/TC 210

GHTF .

4

4.1.

2000 가 4,700 , 가
4 1,400 . 3,300 가
가 .
 ,
가 가 .
가 1991 408
2000 792 1991 236 1998 823
1991 4,234 2000 1 2,665
2005 1 2,900 , 2010
2 6,000 .
가 70% 20
73.9%
1980 , , , MRI, CT
가가 .
 , ,
1998 214 2001 262 , 2004
294 .
1998 105 2001 123 2004 140 ,
1998 4 2001 60 2004 67 , 1998
31 2001 38 2004 43

21

, , , 가 , , , 가

가 .

가
가

.
가

가 . 8

770 (1998)가

11

14 ,

19

가

()

, ,

GMP

, , 가

가 가

가

ISO

4.3. 가

가.

가

1994

가

(19).

(19) 가

가

· The Federal Food, Drug and Cosmetic Act · Medical device
 amendment · Safe Medical Device act · The Food & Drug
 Administration modernization Act · code of federal Regulation 21

· Medical device drective · Active device implotable Medical device
 drective · in vitro Diagnostic Medical device drective

: , 1998 ; , 2001

(20) 가

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가
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: , 1998 ; , 2001

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2, 3 가 3 1

1976 FDC 가
 3 . 1
 가 가 . 2 FDA
 , 3 ,

4

1994 ,
 4 1
 2, 3, 4 (21).

(21) 가

	3 (938)	
	CLASS :313	
2	CLASS :473	
	CLASS :152	
	3 (1,384)	
	CLASS :489	FDA
2	CLASS :744	
	CLASS :151	

(가) CLASS , a, b, 가

2 CLASS , , ,

: , 1995 ; , 1998 ; , 2000

. 가

가

가

가

1

2

, 3

가

. 1

A(가)

, 2

H(

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A

F(

), D(

), E(

)

가

, 3

H

B(

), F, D, E

가

4

H

B, F, D

가

가

, 1

, 2

3

(22).

. 가

가

FDA

7

2

510(K)

가

가

가

(22).

(22) 가 가 가

		가	가
-1	() · 가		
-2	(가) · , ,		
-3	(가) · , ,		-
GMP			
-1	() · 가	FDA,	
-2	() · 510(K) GMP	3	
-3	() · PMA GMP	7	,
	510K; ,	2	
	PMA; , , .	510(K)	
-1	() · 가 가		
-2a	() · 가 + / ()	가	
-2b	() · + / ()	,	-
-3	() · + / ()		
-1	() · 가 GMP		
-2	() · () · GMP	,	
-3	() · () GMP	(7	가 5 , 가 3
-4	() · () GMP)	
()	는 , ,	가	

. ISO9001 GMP 2
 1 GMP .
 ISO9001 GMP CGMP ,
 . FDA , GMP
 . ISO, EN GMP
 ISO EN29000 가
 EN46000 가 . ISO9001 EN46001
 , ISO9002 EN4002 .
 QA ,
 ISO 3
 GMP 1 (23).

(23) 가

GMP		가	
2 1 GMP	-GMP : ISO9001 : GMP ()	1, GMP - GMP:1 -QA :3, 4 - :2, 3, 4 가 2. - :2, 3 가	가
1 GMP	ISO 9001 GMP (CGMP)	2, 3 가	FDA GMP
2 GMP	- H() :ISO9001+ EN46001 - D() :ISO9002+ EN46002	- H:2, 3 - D:2, 3	(NB) GMP
3 1 GMP	QA / : ISO 9001, 2	1. GMP - 2, 3 2. - 2, 3 - 가 가 :2,3 1 GMP GMP	가 가 GMP

: , 1998 ; , 2002 ; , 2002

가

, 가

(24).

(24) 가

<p>8 , 3</p>	<p>()</p>	<p>가</p>		
<p>FDA 3 BSI, UL 8 510(K)</p>	<p>FDA</p>	<p>510(K), PMA GLP</p>	<p>GMP</p>	<p>3 :PMA 가</p>
<p>50 가</p>	<p>MDD</p>	<p>(50)</p>		<p>가</p>
<p>() 가</p>		<p>GLP</p>	<p>가 가</p>	<p>: 3/4 가</p>

: , 1998

4.4.

가 , 가 가

가 가

가 가

가 가

(GHTF)

가 가

가 , 가 , 가 ,

4.5.

가 , , 가

가 .

1994

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가

가

가

가

가

가

가

가

ISO

GMP ,

GMP ,

ISO

3

1

ISO

가

GATT

WTO

가 1993

(GHTF)

가

가

FDA

CE-Marking,

, ISO

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가 가 ,

가 , ,

2002 7

5

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가 가

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가

가

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가

가

1998

가

1998

1995

1998

2000

가 , , 가 (GHTF)
1998

가

가

가

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가

가

가

ISO, FDA, CE-Marking

가

2002 7

가

6

가

, , .
 .
 , 2000 1 2,665 .
 9202 가 (609)가
 (644) 70% 20
 가 2000
 25 2004 294
 21 가가

(WTO)

(GHTF)

가

가
가

가,

. , 2001
 . , 2001
 . FDA . 2002
 , , 2001
 . WTO . , 1995
 , . , 1995
 . . 2002
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 . (MRA) .
 , 2001
 . . 1998
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 가 . ,
 1994 . , 2000
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. , 1999
가 . 2 ; (2000- 2005), 1999
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. , 2001
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. , 1997

HIMA Energe market's report. 1998
Medical device fact book 3th edition,
Year book of world electronic data, 2001

=ABSTRACT =

This study analyzed the current position, the future flow and outlook of medical instrument industry by understanding the present status of the medical instrument industry, the present condition of professional training, and the characteristics of medical instruments in the major countries such as the United States, Europe, and Japan including Korea. Then, the objectives of this study are to draw the major regulatory factors of management system which the major countries possesses by comparing and analyzing through literature review of management system including medical instruments related laws in the major countries and to investigate the adequacy of not only the development plan for the Korean medical instrument management system and the separate law for medical instruments currently driven by the Ministry of Health and Welfare and the Korea Food and Drug Administration.

The important details and study results are as follows.

The Korean medical instrument market has grown to the size of 1,266.5 billion won in 2000, but the import reliance was very high with a total import of 920.2 billion won and the importing companies (644) were more than the manufacturing companies (609).

Also, more than 70% of domestic manufacturing companies have less than 20 employees and the simple medical instruments with low technology such as condoms are suture gauze have relatively high ratio in export items. However, the size of global medical instrument market was 2.5 billion dollars in 2000 and it is estimated to increase to 29.4 billion dollars in 2004. In fact, since the medical instrument industry is recognized as high value added industry, the system and financial support plan to raise it into an independent industry through technology development and export promotion should immediately provided.

In addition, it is required to bring the systematic training of technology development personnel and to construct industry-university-research cooperative system from the developmental stage.

On the other hand, the medical instruments related market is currently regulated by just the Pharmaceutical Law in Korea.

The adequacy of enactment of medical instrument law and its main details are as follows.

First, since GHTF organized by the developed countries such as the United States, Europe, and Japan demands to fit the medical instruments to the national standard through the regulation under the WTO system, the introduction of new management system is urgent because it is hard to operate flexibly the international regulations and technologies within the current Pharmaceutical Law.

Second, since unlike the previous simple medical instruments, the various kinds of high-tech science such as electric, mechanical, physical, and material engineering are applied recently, the current Pharmaceutical Law cannot manage the medical instruments together with the medical supplies. Thus, the establishment of effective management system reflecting the characteristics of medical instruments is required.

Third, the law should be reformed since it is hard to regulate systematically the main regulatory factors of major countries such as terms and definitions, classification, authorization procedure, and quality control in the current Pharmaceutical Law.

Finally, as the medical instruments can give critically adverse effects on the human body, the complement of administrative management system including review, reevaluation, follow-up management, and adverse effect reporting system to assure continuous safety and efficacy has been emphasizing. Moreover, internationally the in-advance management is minimized and the

strict post management system such as safety and efficacy for manufactured products is established. Therefore, the separate law for medical instruments should be enacted because it cannot be complemented under the current Pharmaceutical law system.