2016 바이오미래포럼

Global Innovation Network and Asian Catch-up Models in Bioindustry

Nov. 07, 2016

Seok-Kwan Kim, Ph.D

Director of Division for Industrial Innovation Research,
Science and Technology Policy Institute

STEPI 과학기술정책연구원
SCIENCE AND TECHNOLOGY POLICY INSTITUTE

Big Question

■ Will Asia's success stories go on in bioindustry?

- Asian emerging countries like Korea and China have been making huge success in catching up in most manufacturing sectors.
  - ☞ Can they repeat the same patterns in science-based industry like biopharmaceuticals?

■ Typical Patterns of Asian Industrialization and Pharmaceutical Industry

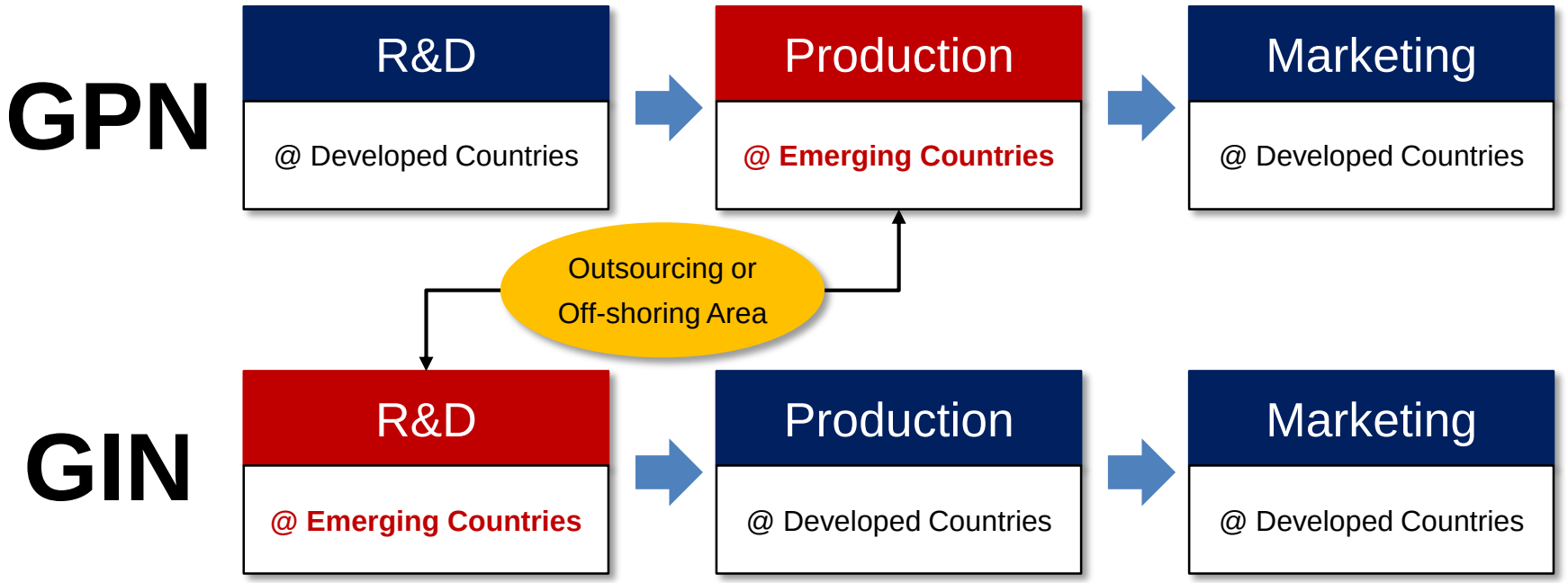
- Asia tapped into **Global Production Network(GPN)** for their industrialization.
- Played a role as production partners in GPN ⇒ earned money, learned manufacturing technologies and built up innovation capabilities
- OEM ⇨ ODM ⇨ OBM*: grown from outsourcing partners to global companies
- But there was nearly no GPNs in pharmaceutical industry!
  - ☞ It was out of typical catch-up paths that other sectors followed.

➡ How can Asian countries catch up in bioindustry?

* OEM: Original Equipment Manufacturing
  ODM: Own Design Manufacturing
  OBM: Own Brand Manufacturing

GIN Can Be an Answer

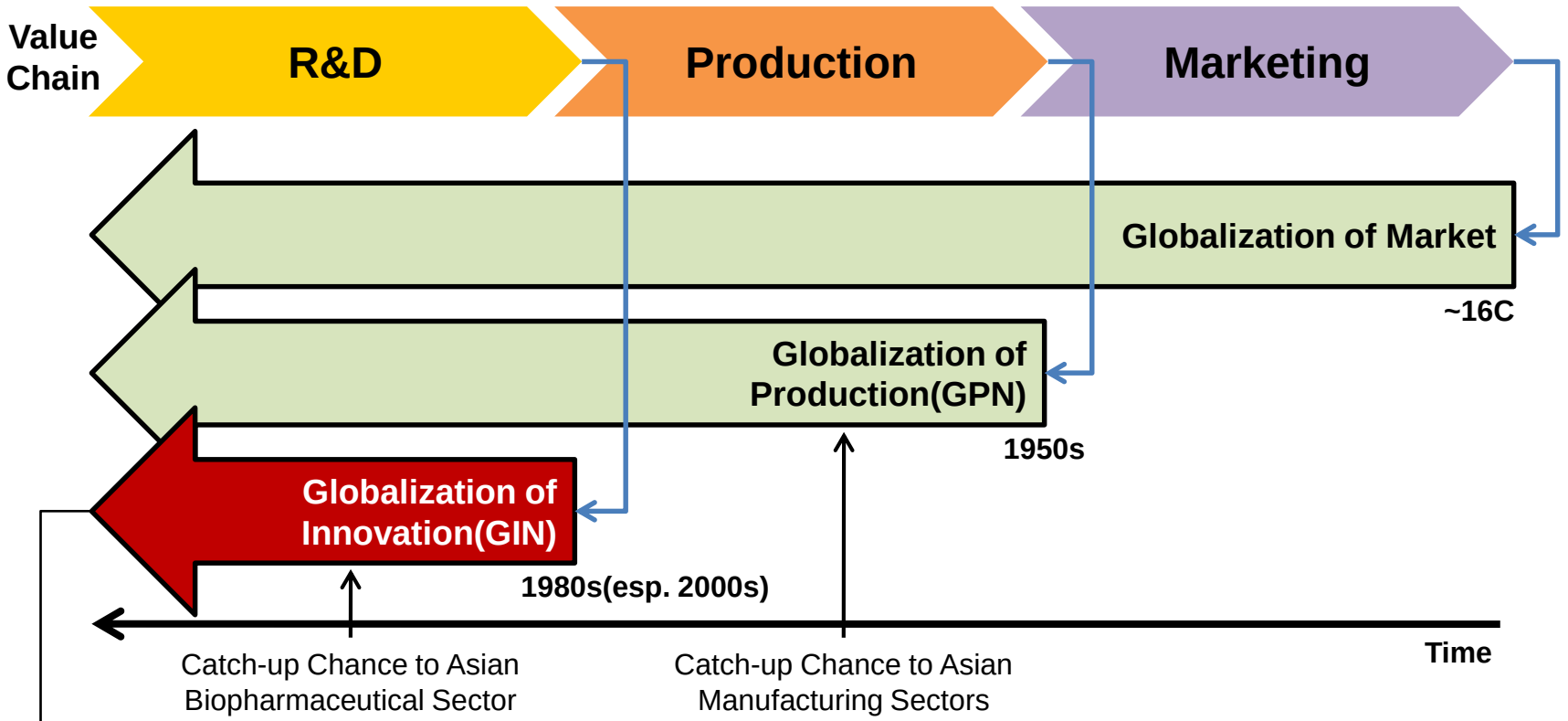
■ Definition of **GPN**(Global Production Network) & **GIN**(Global Innovation Network)



■ The rise of GIN in pharmaceutical industry opens a window of opportunity.

☞ Asia can make use of GIN as a catch-up strategy in pharmaceutical industry!

Globalization and Evolution of GVC(Global Value Chain)



① R&D Off-shoring : Mainly in IT Sector, >6,000 R&D Centers of Foreign Firms in China

② R&D Outsourcing : Actively Rising in Pharmaceutical Sector

③ Diaspora Network and Returnees: Critical Role in Innovation at China, Taiwan, India

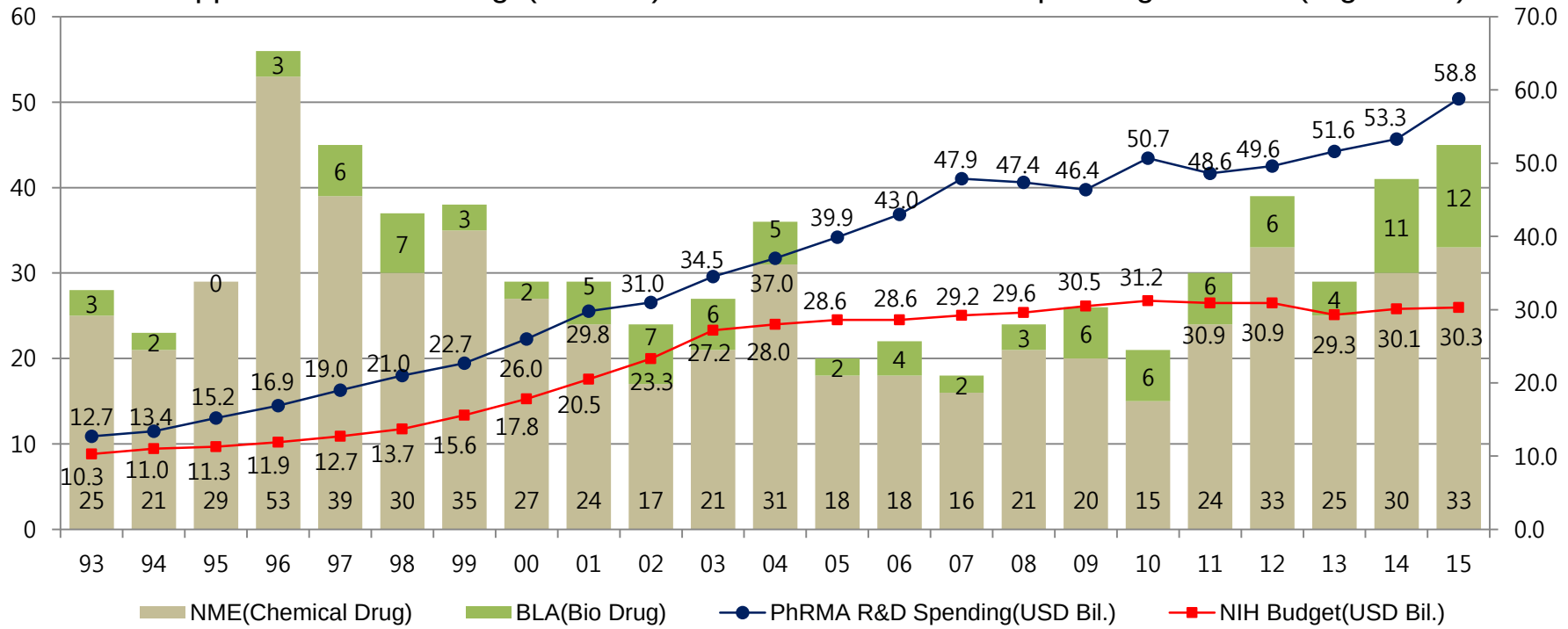
☞ "We really will see the beginning of "the globalization of innovation". More and more American and European companies are outsourcing significant R&D tasks to India, Russia, and China" - Thomas Freidman(2005), *The World is Flat* , p.30.

Drivers of GIN in Pharmaceutical Industry

■ Big Pharmas have been suffering serious R&D productivity problem

- R&D spending is rising on, but # of approved drug decreases or stagnates

FDA Approvals of New Drugs(Left/Bar) VS. Private/Public R&D spending in the US(Right/Line)



Source: FDA CDER, New Molecular Entity(NME) Drug and New Biologic Approvals, each year(www.fda.gov/Drugs)
PhRMA, Industry Profile, each year(www.phrma.org/profiles-reports)
NIH, History of NIH Appropriations(www.nih.gov/about-nih/what-we-do/budget)

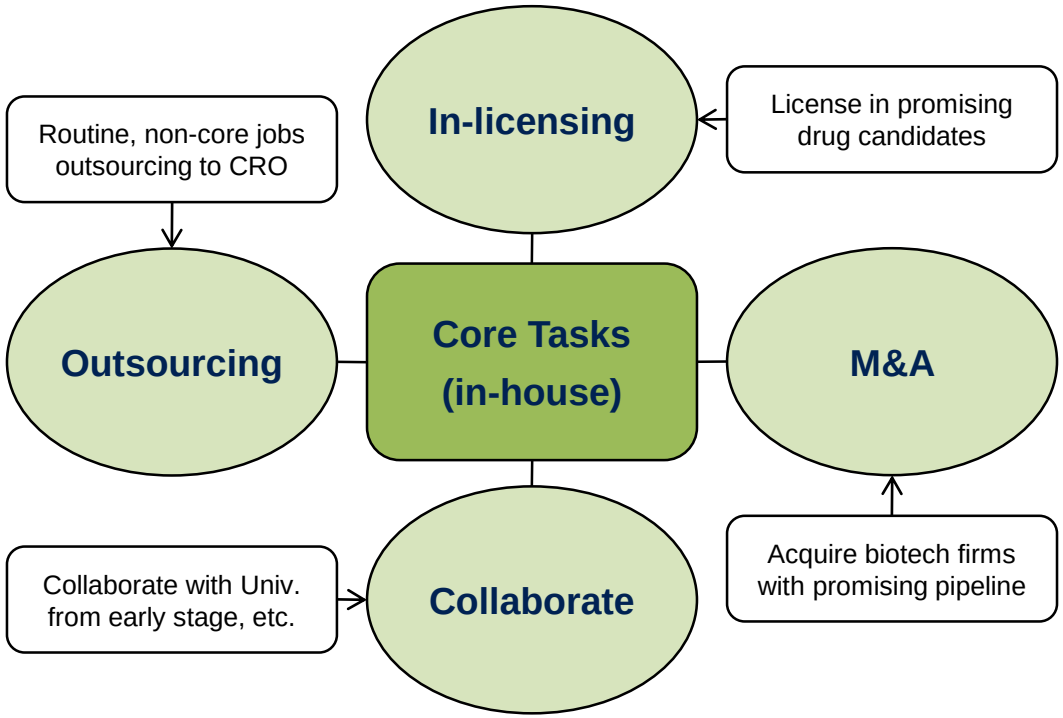
STEPI 과학기술정책연구원 SCIENCE AND TECHNOLOGY POLICY INSTITUTE

Rise of Networked Pharma Model

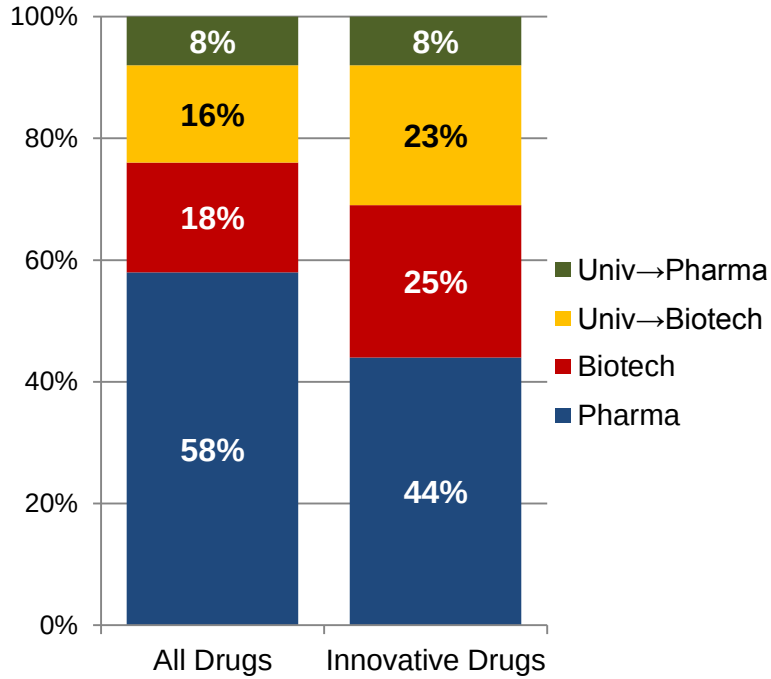
■ "Networked Pharma Model": a solution to the R&D productivity problem

- Purpose: To cut down cost and maximize output
- Share of drugs discovered in-house in total sales of US top 20 companies dropped from 80%('80) to 45%('02)
- "Companies are in-licensing and out-licensing like crazy" - Editor of *Recombinant Capital*

Networked Pharma Model



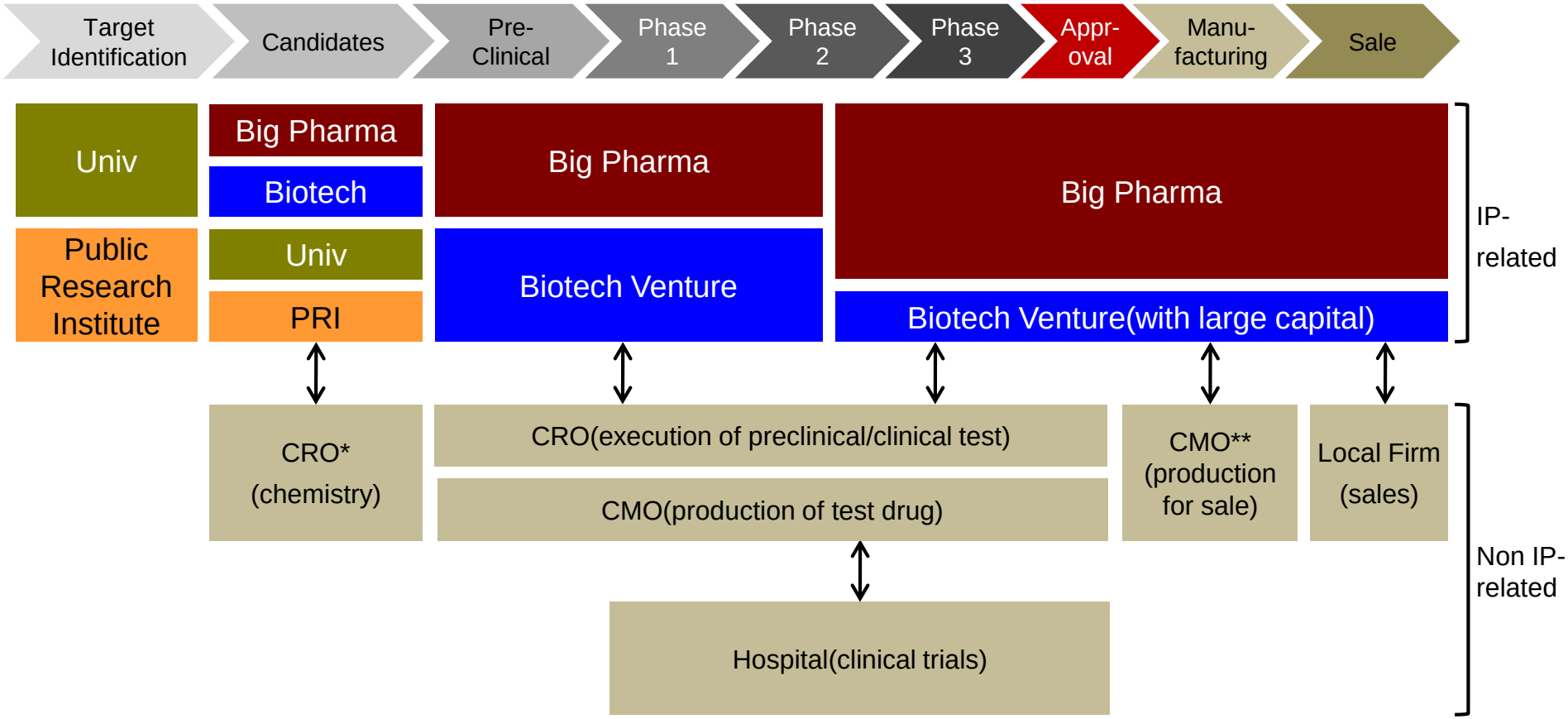
Origins of New Drugs(1998-2007)



Note: Total 252 drugs FDA approved during 1998-2007
Source: Nature Reviews Drug Discovery, Vol.9(2010): 867-82

STEPI 과학기술정책연구원 SCIENCE AND TECHNOLOGY POLICY INSTITUTE

Structure of Drug R&D Value Chain



* CRO: Contract Research Organization
** CMO: Contract Manufacturing Organization

Another Driver of GIN

■ Scientific capabilities of emerging countries are expanding rapidly.

SCI Papers in Life Sciences

′08 Rank	Ciuntry	'94-'97	'98-'01	'02-'05	'06-'08
1	USA	262,050	314,652	351,928	184,383
2	Japan	51,417	66,233	66,806	47,799
3	UK	54,147	63,619	64,557	48,057
4	**China**	4,190(24)	11,571(13)	25,527(8)	38,901(5)
5	Germany	43,263	55,024	58,110	45,293
6	France	37,551	44,076	42,853	32,405
7	Canada	27,336	30,275	33,566	28,456
8	Italy	24,043	30,147	33,424	27,001
9	Spain	15,001	20,638	24,484	21,548
10	Australia	15,569	19,922	22,093	18,845
11	**Korea**	4,175(23)	9,103(20)	14,155(13)	15,203(12)
12	Brazil	4,961	9,116	13,393	14,358
13	Netherlands	16,938	19,193	20,419	16,507
14	**India**	8,285(14)	10,005(15)	12,715(16)	13,983(16)
15	Sweden	13,990	16,368	17,087	13,077

Foreign Students at US Univ.

09/10 Rank	Home Country	2008/09	2009/10	09/10 share(%)
1	**China**	98,235	127,628	18.5
2	**India**	103,260	104,897	15.2
3	**Korea**	75,065	72,153	10.4
4	Canada	29,697	28,145	4.1
5	Taiwan	28,065	26,685	3.9
6	Japan	29,264	24,842	3.6
7	Saudi Arabia	12,661	15,810	2.3
8	Mexico	14,850	13,450	1.9
9	Vietnam	12,823	13,112	1.9
10	Turkey	12,148	12,397	1.8
	Total	671,616	690,923	100

Increasing Role of Asia in Global Alliance

Rank	2000		2001		2002		2003		2004	
	Country	Count	Country	Count	Country	Count	Country	Count	Country	Count
1	USA	2,176	USA	2,447	USA	2,650	USA	2,737	USA	3,112
2	UK	249	UK	339	UK	364	UK	374	UK	462
3	Germany	151	Canada	256	Germany	240	Germany	325	Germany	370
4	Canada	149	Germany	229	Japan	231	Japan	220	Japan	273
5	Japan	142	Japan	210	Canada	214	Canada	208	Canada	259
6	Switzerland	97	Switzerland	135	Switzerland	138	Switzerland	148	Switzerland	187
7	France	54	France	109	Australia	129	France	121	Australia	141
8	Australia	51	Australia	68	France	121	Australia	113	France	140
9	Denmark	41	Netherlands	59	Sweden	73	Netherlands	81	Netherlands	112
10	Ireland	39	Sweden	56	Denmark	69	Sweden	78	Denmark	88
11	Netherlands	37	Denmark	52	Netherlands	62	Denmark	63	**India**	**83**
12	Sweden	33	Belgium	46	Belgium	45	**India**	**54**	Sweden	78
13	Italy	26	Italy	41	**India**	**42**	Israel	44	Belgium	59
14	Belgium	23	Ireland	40	Israel	39	Belgium	42	Italy	59
15	Israel	20	**India**	**34**	Italy	38	Italy	32	Israel	48
16	**India**	**17**	Israel	30	**South Korea**	**24**	**South Korea**	**28**	Ireland	33
17	**South Korea**	**17**	Spain	19	Ireland	23	Singapore	25	**South Korea**	**32**
18	Norway	12	Taiwan	12	Finland	15	Finland	23	**China**	**28**
19	Finland	10	China	9	China	14	China	22	Spain	26
20	**China**	**5**	Finland	9	Norway	14	Spain	22	Finland	26
21	Spain	5	**South Korea**	**8**	Spain	13	Ireland	19	Austria	14
22	Taiwan	4	New Zealand	8	New Zealand	12	Taiwan	17	Singapore	10

Source: MedTrack DB

Increasing Role of Asia in Global Alliance

Rank	2005		2006		2007		2008		2009		1990-2009	
	Country	Count	Country	Count	Country	Count	Country	Count	Country	Count	Country	Count
1	USA	3,181	USA	3,265	USA	3,150	USA	3,201	USA	2,906	USA	34,912
2	UK	468	UK	526	UK	435	UK	466	UK	515	UK	4710
3	Japan	404	Germany	357	Germany	287	Germany	350	Canada	283	Germany	3308
4	Germany	364	Japan	323	Japan	235	Canada	258	Germany	275	Japan	2955
5	Canada	277	Canada	316	Canada	235	Japan	237	Japan	231	Canada	2800
6	Switzerland	225	Switzerland	197	France	188	**India**	**206**	Switzerland	208	Switzerland	1969
7	Australia	148	Australia	153	Switzerland	184	Switzerland	189	France	207	France	1620
8	Netherlands	140	France	145	**India**	**146**	France	176	**China**	**207**	Australia	1297
9	**India**	**119**	**India**	**145**	Netherlands	135	**China**	**175**	Australia	147	Netherlands	1072
10	France	118	Netherlands	132	Australia	118	Australia	143	**India**	**136**	**India**	**1008**
11	Sweden	81	Israel	94	Israel	101	Sweden	123	Sweden	132	Sweden	886
12	Denmark	79	Belgium	92	**China**	**92**	Netherlands	119	Netherlands	129	Denmark	813
13	Belgium	78	Denmark	76	Sweden	87	Denmark	88	Denmark	101	Belgium	677
14	Israel	65	Sweden	74	Italy	79	**South Korea**	**81**	Italy	101	Israel	646
15	Italy	54	Italy	59	Denmark	74	Israel	74	Israel	84	**China**	**636**
16	**South Korea**	**47**	Spain	54	Belgium	68	Belgium	72	**South Korea**	**83**	Italy	611
17	**China**	**34**	**South Korea**	**46**	**South Korea**	**56**	Italy	69	Belgium	71	**South Korea**	**463**
18	Ireland	31	**China**	**42**	Spain	50	Ireland	44	Spain	62	Ireland	407
19	Spain	30	Ireland	39	Ireland	33	Spain	41	Ireland	40	Spain	350
20	Singapore	28	Singapore	30	Singapore	17	Finland	33	Singapore	32	Finland	220
21	Austria	22	Finland	27	Austria	17	Taiwan	33	Norway	30	Singapore	179

Source: MedTrack DB

Global Top 50 Pharma Companies(2014)

Rank	Company	Country	Rx Sales (USD bil)	R&D spend (USD mil)	Rank	Company	Country	Rx Sales (USD bil)	R&D spend (USD mil)
1	Novartis	Switzerland	46.1	9,301	26	Celgene	USA	7.5	1,848
2	Pfizer	USA	44.5	7,152	27	Otsuka Holdings	Japan	6.9	1,528
3	Roche	Switzerland	40.1	8,614	28	Allergen	USA	6.2	1,078
4	Sanofi	France	38.2	6,200	29	Les Laboratoires Servier	France	5.9	1,625
5	Merck & Co.	USA	36.6	6,532	30	Shire	Ireland	5.8	840
6	Johnson & Johnson	USA	30.7	6,031	31	Abbott Laboratories	USA	5.1	129
7	GlaxoSmithKline	UK	30.3	4,866	32	Sun Pharmaceutical Industries	India	5.0	288
8	AstraZeneca	UK	25.7	4,941	33	Valeant Pharmaceuticals Intl.	Canada	5.0	246
9	Gilead Sciences	USA	24.5	2,737	34	CSL	Australia	4.7	377
10	AbbVie	USA	19.9	3,252	35	Eisai	Japan	4.4	1,158
11	Amgen	USA	19.3	4,124	36	UCB	Belgium	3.7	1,233
12	Teva	Israel	17.5	1,488	37	Fresenius	Germany	3.7	368
13	Bayer	Germany	16.4	2,495	38	Chugai Pharmaceutical	Japan	3.6	684
14	Eli Lilly	USA	16.3	4,380	39	Menarini	Italy	3.4	N/A
15	Novo Nordisk	Denmark	15.8	2,452	40	Grifols	Spain	3.3	232
16	Boehringer Ingelheim	Germany	13.9	3,151	41	Aspen Pharmacare	South Africa	3.1	2
17	Takeda	Japan	13.0	3,179	42	Hospira	USA	3.0	344
18	Bristol-Myers Squibb	USA	11.9	3,913	43	Sumitomo Dainippon Pharma	Japan	2.9	663
19	Actavis	Switzerland	11.1	1,086	44	Mitsubishi Tanabe Pharma	Japan	2.9	647
20	Astellas Pharma	Japan	10.4	1,855	45	STADA Arzneimittel	Germany	2.4	73
21	Baxter International	USA	8.7	1,164	46	Mallinckrodt	Ireland	2.3	167
22	Biogen Idec	USA	8.2	1,893	47	Endo International	Ireland	2.2	58
23	Merck KGaA	Germany	7.7	1,815	48	Alexion Pharmaceuticals	USA	2.2	404
24	Mylan	USA	7.6	564	49	Lundbeck	Denmark	2.2	499
25	Daiichi Sankyo	Japan	7.6	1,683	50	Kyowa Hakko Kirin	Japan	2.2	451

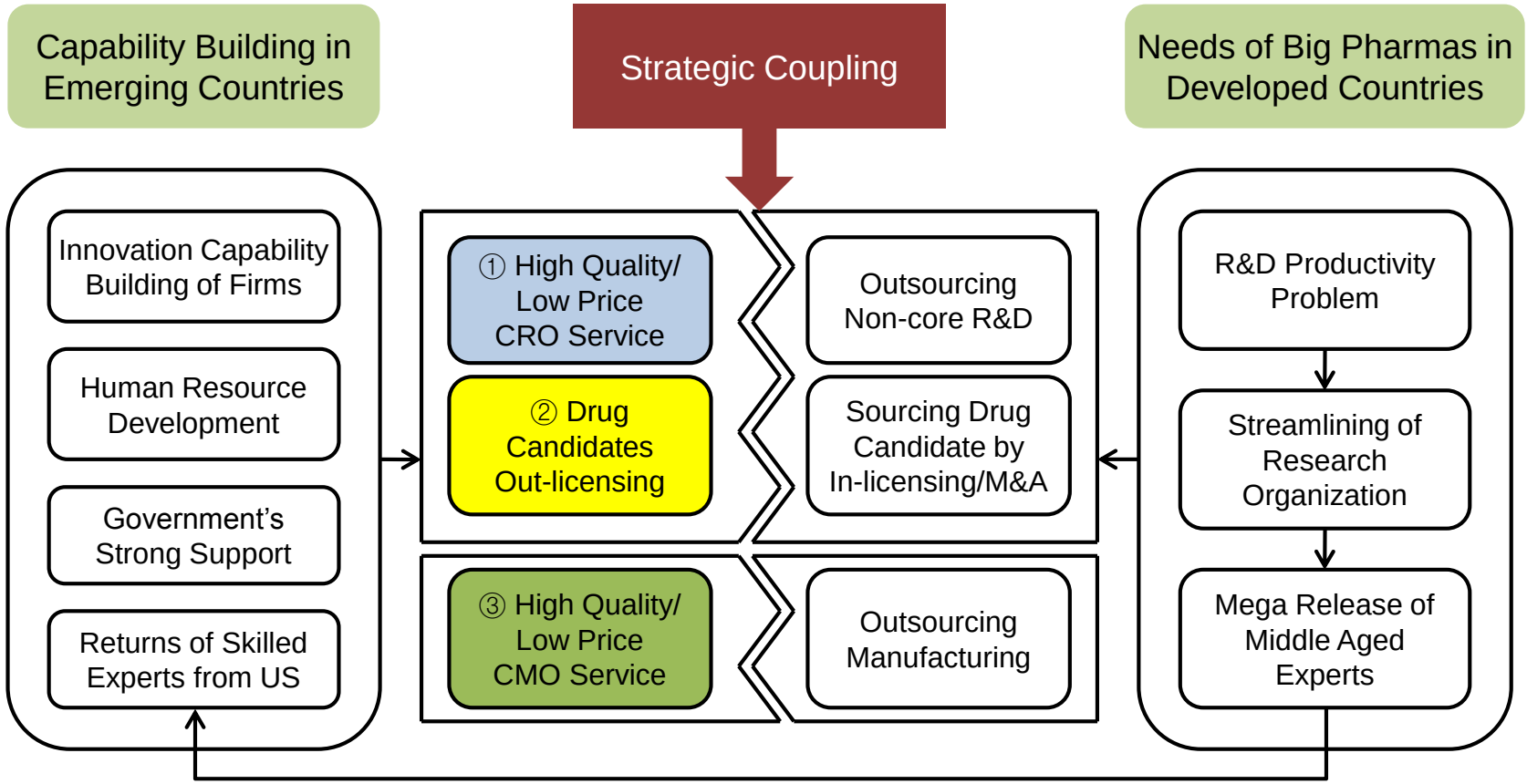
Source: “Pharm Exec’s Top 50 Pharma Compnies”, *Pharmaceutical Executive* Vol.35, Iss.6 (Jul 4, 2015) (www.pharmexe.com)

▪Asian Companies: 9 Japanese, 1 Israeli, 1 Indian, 0 Chinese, 0 Korean

☞ China, Korea and India, despite their weak market positions, have grown as important alliance partners.

3 Catch-up Models in GIN/GPN

■ 3 strategic models that companies in emerging countries can adopt:
① CRO, ② Licensing-out, and ③ CMO

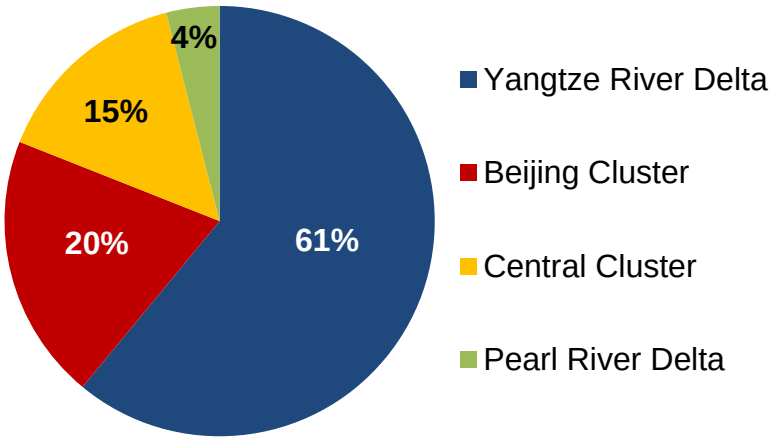


※ This strategic coupling framework is based on Manchester geographers' work on GPN

Strategy 1: CRO Model(China)

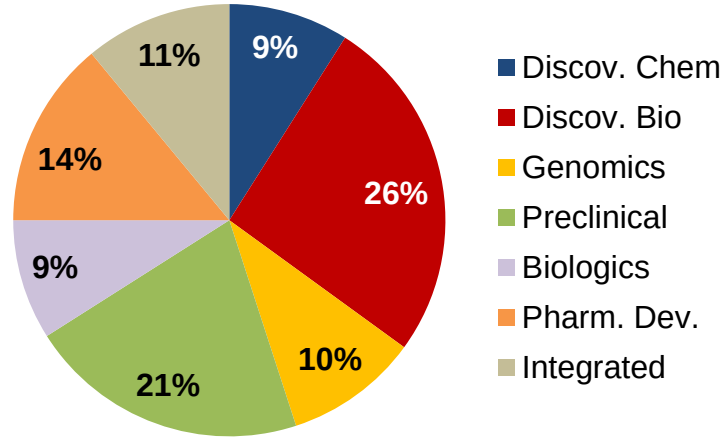
- Over 300* CROs are active in China(Shi et al., 2014)**
  - They provide contract research services for MNCs and local players in nonclinical and clinical areas.
  - In 1996, 1st CRO has started in clinical areas, but more CROs are focusing on nonclinical areas now.
  - A few big CROs are leading the market: Wuxi AppTec(10,000 employees), Pharmaron(3000), Chempartner(2,000), Genscript(1,300), Asymchem(1,300), GL Biochem(1,000)

Locations of Major 66 Nonclinical CROs



Source: Drug Discovery Today, Vol.20, No7(2015): 794-8.

Service Areas of Major 66 Nonclinical CROs



Source: Drug Discovery Today, Vol.20, No7(2015): 794-8.

* 447 Chinese CROs(Shanghai 151, Beijing 63) are listed in www.contractresearchmap.com

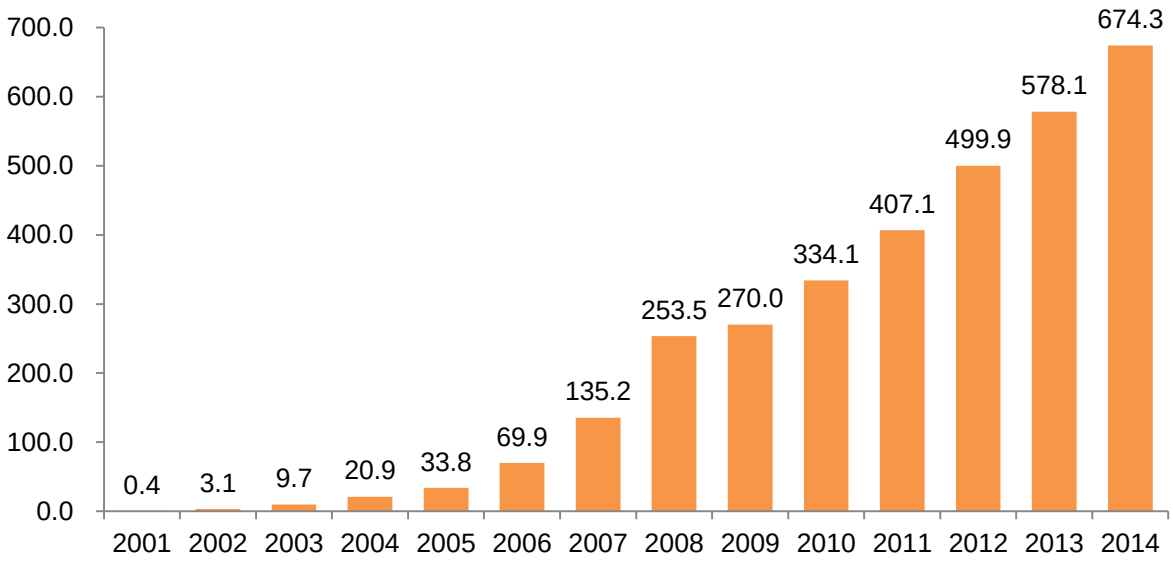
** Shi et al.(2014), "CROs in China: Integrating Chinese R&D Capabilities for Global Drug Innovation", *Globalization and Health* 2014, 10:78

WuXi AppTec: the Largest CRO in China

Company Profile

- Founded in 2000 as a chemistry CRO. Listed on NYSE in 2007
- About 10,000 employees are working for over 1,600 customers around the world in 2016
- 2014 Revenue: USD 674mil., Operating Income: USD 104mil.
- Current service coverage: all nonclinical, clinical, and manufacturing services for chemical drugs, biologics, cell & gene therapy, and medical device

Remarkable Revenue Growth of WuXi AppTec(USD mil.)



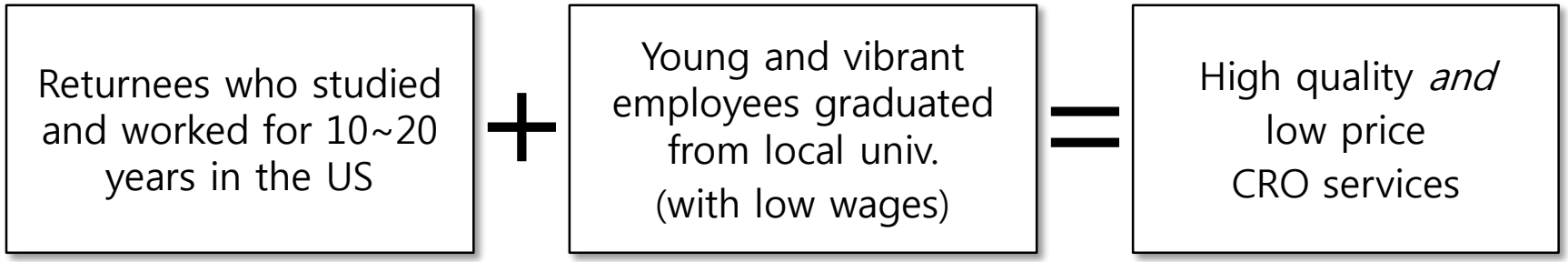
Source: 'Press Releases' at WuXi AppTec Hompage(http://www.wuxiapptec.com/com_press.html)

WuXi AppTec's Executive Leadership

	▪ **Ge Li, Ph.D**. (born in 1967) ▪ Founder, Chairman and CEO ▪ BS in Chemistry from Beijing Univ. ▪ PhD in Organic Chemistry from Columbia Univ. ▪ Co-Founder of Pharmacopeia, worked 8 years there		▪ **Edward Hu** ▪ Chief Financial Officer, Chief Investment Officer ▪ MBA & MS in Chemistry from Carnegie Mellon Univ. ▪ Former Senior Vice President & COO at Tanox
	▪ **Steve Yang, Ph.D.** ▪ Executive Vice President and Chief Operating Officer ▪ PhD in Pharmaceutical Chemistry from UCSF ▪ Former Vice President at AstraZeneca and Pfizer		▪ **Xiaozhong Liu** ▪ Co-Founder, Executive Vice President ▪ BS from Beiking Univ., EMBA from China Europe International Business School
	▪ **Shuhui Chen, Ph.D.** ▪ Chief Scientific Officer ▪ PhD in Organic Chemistry from Yale Univ. ▪ Former Research Adviser at Eli Lilly and BMS ▪ **18 years experience in Medicinal Chemistry**		▪ **Suhan Tang, Ph.D.** ▪ Chief Manufacturing Officer ▪ PhD in Organic Chemistry from Columbia Univ. ▪ Former Principal Scientist at Schering-Plough ▪ **19 years experience in Development Manufacturing**
	▪ **Zhaohui Zhang** ▪ Co-Founder, Senior Vice President of Operations ▪ EMBA from China Europe International Business School ▪ Former Vice President of WuXi AppTec		▪ **Ning Zhao, Ph.D.** ▪ Co-Founder, Senior Vice President of Operations ▪ Ph.D. in Analytical Chemistry from Columbia Univ. ▪ Worked at BMS, Pharmacopeia, Wyeth
	▪ **Minzhang Chen, Ph.D.** ▪ Senior Vice President of Process R&D and Mfg ▪ PhD in Organic Chemistry from Univ. of Minnesota ▪ Former Director at Vertex Pharmaceuticals Inc. ▪ **18 years experience in Process R&D & API Mfg**		▪ **Chris Chen, Ph.D.** ▪ Senior Vice President and CTO, Biologics Services ▪ PhD from University of Delaware ▪ Former Director at Eli Lilly, Manager at Merck ▪ **16 years experience in Large Scale Cell Culture Dev.**
	▪ **Alex Fowkes** ▪ Senior Vice President, Head of Commercial Operations ▪ BS in pharmacology from the Univ. of Queensland and LLB from Bond Univ. ▪ Former Executive Director at Pfizer		▪ **Richard M. Soll, Ph.D.** ▪ Senior Vice President of International Discovery Service ▪ Ph.D. in Chemistry from Dartmouth College ▪ Former Vice President and CSO at TargeGen ▪ **25 years experience in Drug Discovery and Dev.**

Source: 'Executive Leadership' at WuXi AppTec Hompage(http://www.wuxiapptec.com/com_mngmnt.html)

Key Success Factors of WuXi AppTec



- Hired over 100 returnees with good educational backgrounds and rich industry experiences in the US
  - They graduated from Brandeis, Columbia, Dartmouth, Harvard, NYU, Northwestern, Yale, etc.
  - They worked for 10~20 years at Pfizer, Novartis, Merck, SmithKline Beecham, Roche, Eli Lilly, Bristol-Myers Squibb, Upjohn, Wyeth, Schering-Plough, Genentech, Biogen Idec, Boston Scientific, General Electric, Medtronic, Pharmacopeia, Tanox, TargeGen, Wellcome Biotech, etc.

  ☞ Could provide services at 35~40% of US price with same quality of global standards

- Customer oriented services such as FTE(Full Time Equivalent) program
  - A team of ~10 fill-time staffs is dedicated to one customer company for the contracted periods.
  - Normally renewed every 3 years
  - For customers' perspective, it is like running a branch lab. with 1/3 cost
  - Easy to protect IP and keep informations on chemicals secret
  - About a half of WuXi's revenue comes from FTE program

Implications on Chinese Bioindustry

CRO can be a Good Starting Point for China

- Can start a business with small capital
- Stable revenues with low risk (relative to drug discovery startups)
- Can make synergies between returnees and local talent pool

Technology Learning, Capability Building, and Spillovers to Chinese Ecosystem

- Learn technologies and R&D management practices through business relationship with global clients
- Capability building in all stages of drug discovery and development processes

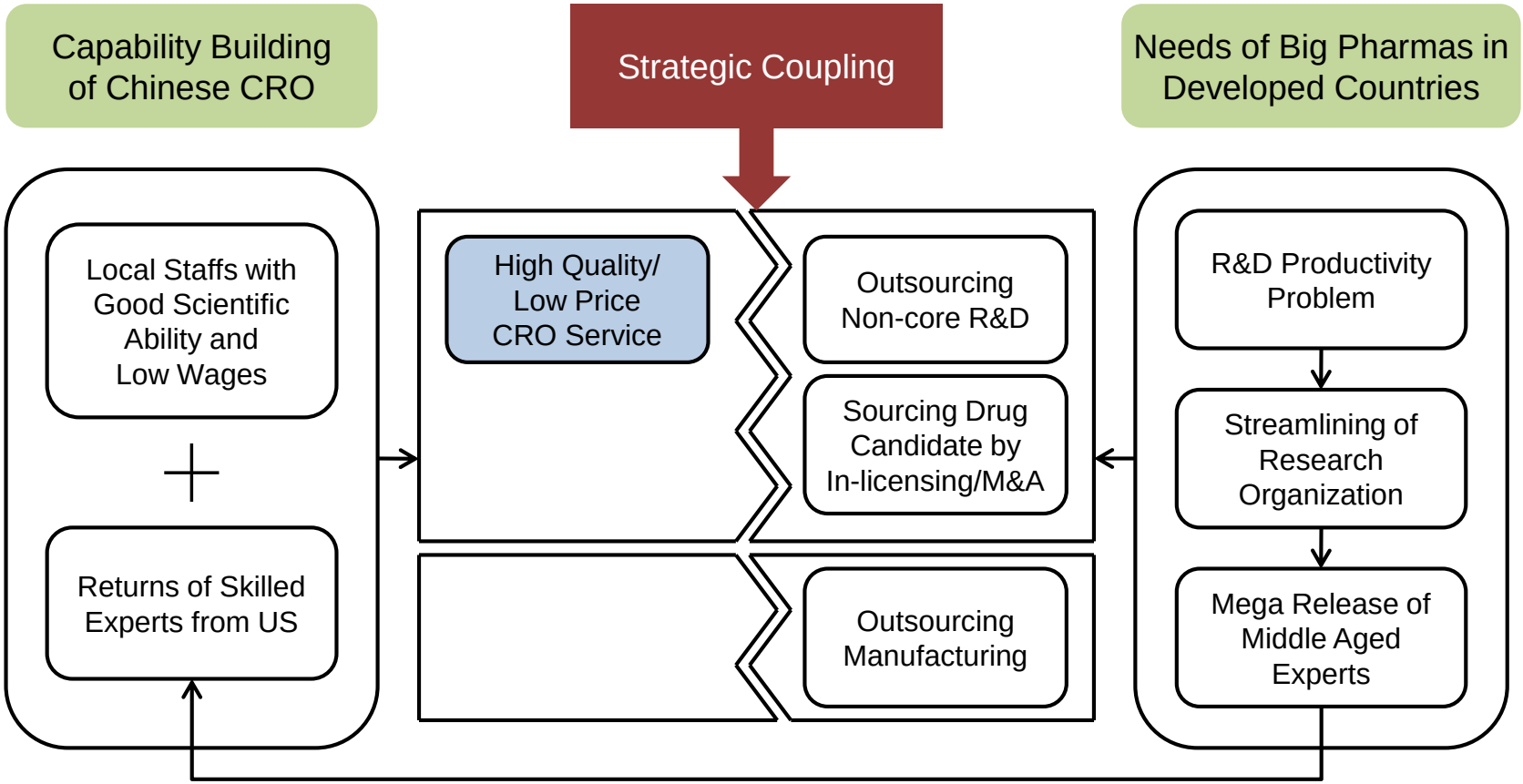
  ⇒ Can be transformed into drug discovery company at any time!
- Knowledge transfers through various mechanisms
  - Active linkages and collaborations between CROs and local universities or companies
  - Mobility of skilled personnel
  - Spin-offs of various startups(specialized CRO, drug discovery company, etc.) from leading CROs

From 'World's Factory' to 'World's Lab' or 'Locus of Innovation'

- Wuxi AppTec is a large "Discovery Engine" – Ge Li, Founder and CEO of WuXi AppTec
- "For us, China is not about outsourcing and cheap labor. Within 5 to 10 years we will be moving **from 'made in China' to 'discovered in China'**." - Moncef Slaoui(GSK's Chairman of R&D), *Financial Times*, 13 Dec 2007

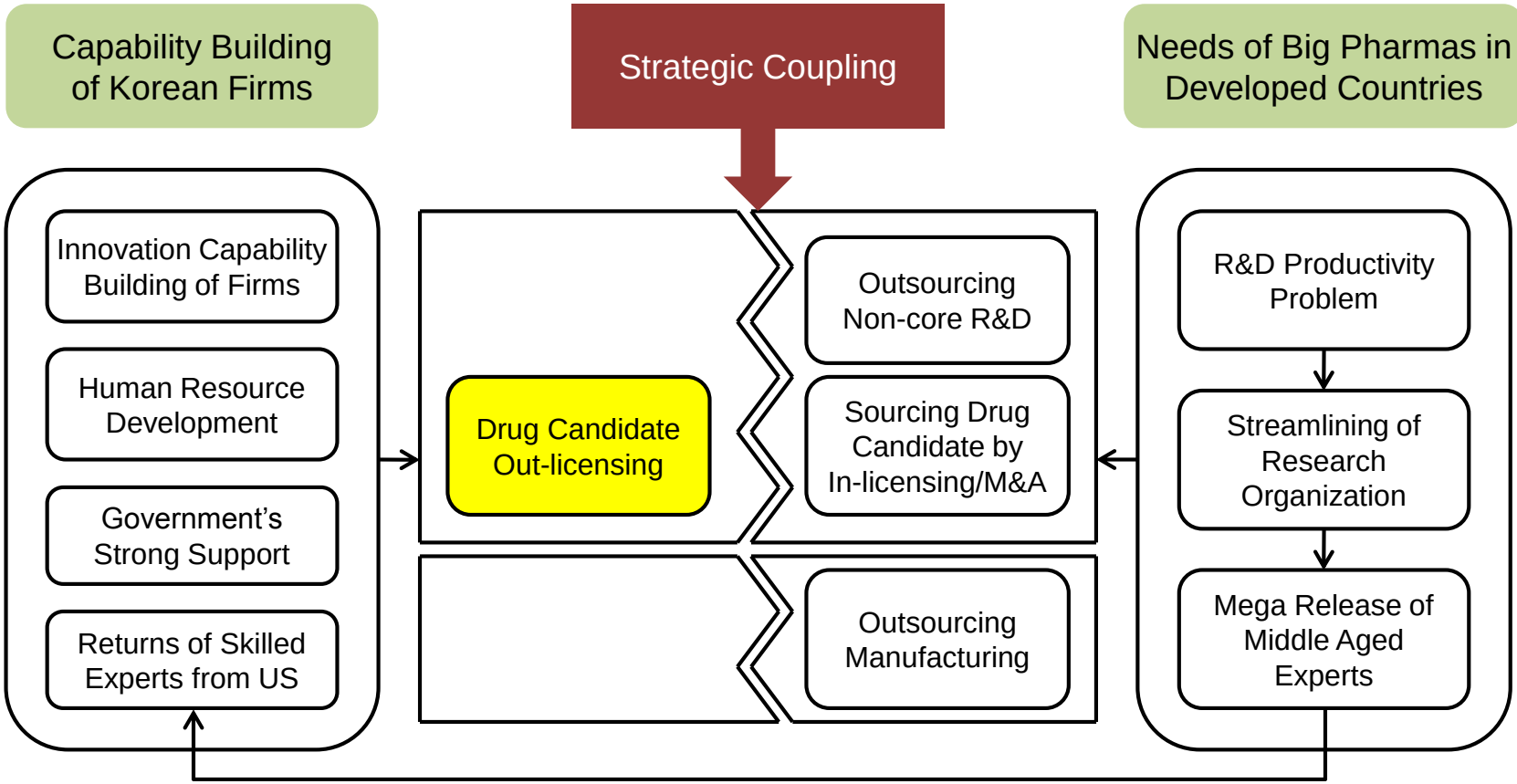
Summary of Chinese CRO Model

■ High Quality / Low Price CRO Service Model



Strategy 2: Licensing-out Model(Korea)

■ Discovering promising drug candidates and licensing them to big pharmas



Status of Korean Pharmaceutical Firms

Top 20 Pharmaceutical Firms in Korea

Rank	Company	Revenue (2015) (KRW bil)	Net Profit (2015) (KRW bil)	R&D Spending (KRW bil)		Employee (2015)
				2014	2015	
1	Hanmi	1,318	162.3	152.5	187.2	2,095
2	Yuhan	1,129	126.0	58.0	72.6	1,594
3	Green Cross	1,048	95.7	84.6	101.9	1,766
4	Kwangdong	956	35.8	5.9	6.3	888
5	Daewoong	840	35.7	98.8	109.1	1,378
6	Celltrion	603	158.2	136.7	112.5	1,074
7	Jeil	595	9.7	16.8	20.3	1,087
8	Chongkundang	593	-6.8	74.7	91.4	1,903
9	DongaST	581	48.6	64.4	57.4	1,591
10	Ildong	476	21.3	37.3	50.9	1,449
11	LG Life Science	451	11.4	80.2	77.9	1,367
12	JW Pharmaceutical	434	2.0	29.7	29.1	1,095
13	Boryung	401	20.3	25.8	29.7	1,068
14	Handok	359	2.2	15.9	18.9	883
15	DongKook	260	27.3	9.6	10.1	757
16	Huons	245	40.5	9.8	13.4	541
17	Donghwa	223	5.6	14.7	13.3	688
18	Samjin	217	27.0	13.9	15.7	635
19	Daewon	216	17.3	15.9	16.7	741
20	Ahngook	198	10.3	21.3	15.8	606

Note: 1USD ≒ 1,100KRW
Source: http://dart.fss.or.kr/
http://www.newsmp.com/news/articleView.html?idxno=150710
http://www.bokuennews.com/news/article.html?no=125081

- Korean pharmaceutical firms can't afford enough R&D money to complete the entire new drug development process from discovery to clinical trials.
- Especially, they can't conduct phase 2 or 3 clinical trials in global scale because they don't have enough money.
- For Korean firms under the obvious budget constraint, the rise of networked pharma model and GIN opens new windows of opportunity!

Strategic Consensus: 2a Licensing Model

2a Licensing Strategy

- To discover a drug candidate, develop it up to phase 2a* clinical trials, and license it to big pharmas
  * phase 2a: optimal licensing point that can maximize benefits with modest cost

Interview Results with Directors of R&D Center of Major Pharmaceutical Firms in 2004-06

Strategic Group	Major Business Model	New Drug Dev. Strategy	Strong Point	Interviewed Companies
Local Pharma	▪ Domestic Marketing for MNCs ▪ OTC and Generic ▪ New Drug Dev. for Domestic Market	▪ Discover Promising Candidates ▪ License-out to Big Pharmas ▪ Develop through Alliance with Big Pharmas	Manufacturing and Marketing Capability in Domestic Market	DongA, Yuhan, Hanmi, Daewoong, JW, CKD, Donghwa
Affiliates of *Chaebol*			Rich Capital, R&D Intensity	LG Life Science, SK, SK Chemicals, CJ
Biotech Venture Firms	▪L/O drug Candidate ▪Contract Research		Innovative Corporate Culture	Crystal, Viromed, Genexcell, Neurotech

Gilead Sciences: Role Model of All Korean Firms

- Founded in 1987, it began to grow rapidly since licensing-out Tamiflu to Roche in 1996.
  * The inventor of Tamiflu is a Korean chemist Dr. Jeong-Eun Kim, a Korean resident in Japan.
- Grown to 9th largest pharma company(2014) with more than 20 FDA-approved drugs.

Achievements of Licensing-out Model

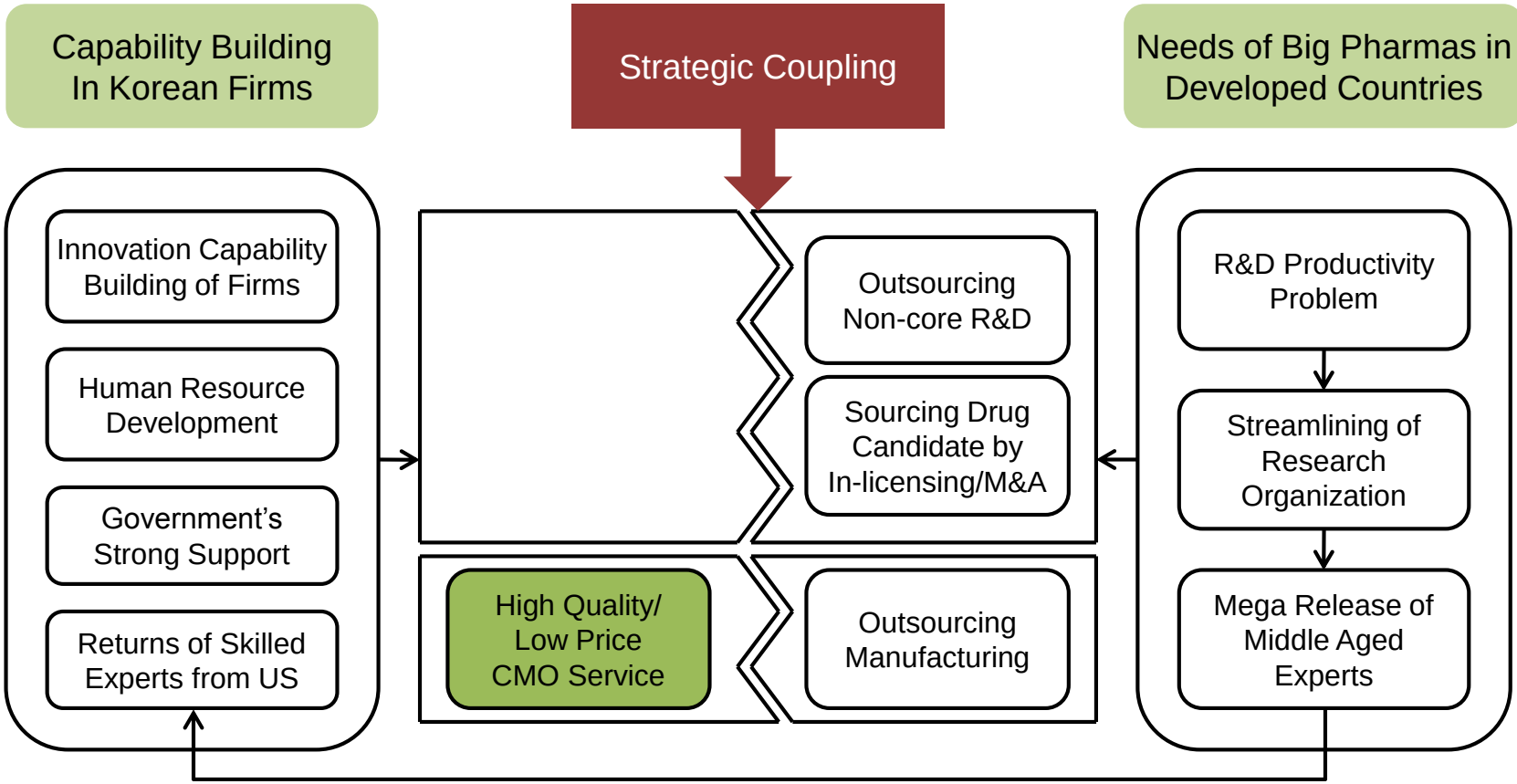
- In 2003, LG Life Science's Factive received FDA approval, but was commercially unsuccessful.
- There've been over 10 deals with deal size >USD100mil., but all dropped in clinical trials.
- **In 2015, Hanmi's 5 mega deals escalate expectations on the success of L/O model**

Date	Partner	Product	L/O Phase	Terms of Deal		
				Upfront	Milestone	Running Royalty
2015.03.05	Spectrum Pharmaceuticals	Targeted Anticancer Drug (Poziotinib)	Phase 2	N/A	N/A	N/A
2015.03.19	Eli Lilly	Immune Disease Drug (HM71224)	Phase 1	$50mil.	$640mil.	2 digit
2015.07.28	Boehringer Ingelheim	Targeted Therapeutics to Resistant Lung Cancer (HM61713)	Phase 1/2	$50mil.	$680mil.	2 digit
2015.11.05	Sanofi	Quantum Project(3 Diabetes Drugs with RAPSCOVERY Technology)		€400mil.	€3,500mil.	2 digit
2015.11.09	Janssen	Diabetes/Obesity Drug with RAPSCOVERY Technology (M12525A)	Phase 1	$105mil.	$810mil.	2 digit
Total(1Euro=1.13Dollor)				$657mil.	$6,085mil.	

Source: 'Press Release' of Hanmi Open Innovation Site(http://oi.hanmi.co.kr)

Strategy 3: CMO Model(Korea)

■ 2 Korean companies(Celltrion & Samsung) have adopted CMO strategy.



CMO Strategies of 2 Companies

■ Strategies and Current Activities of Each Company

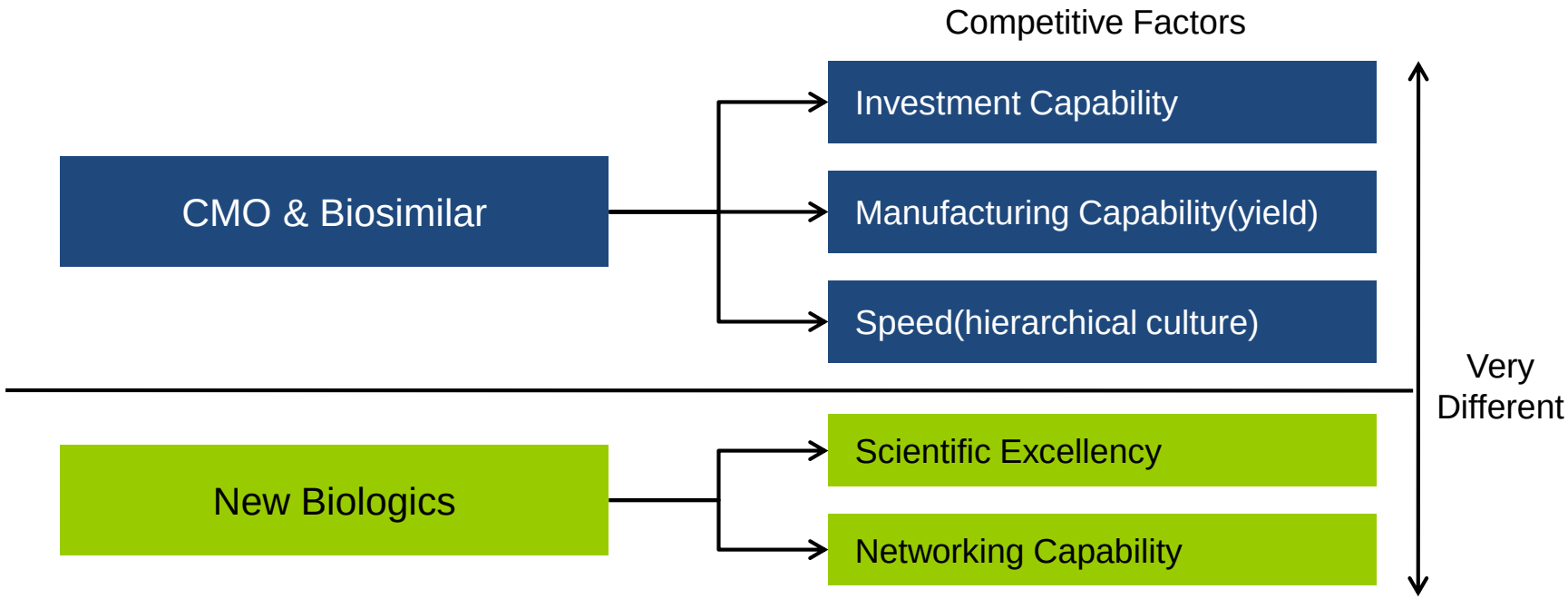
Company	Celltrion	Samsung Biologics/Bioepis
Strategic Path	CMO → Biosimilar → New Biologics(Antibody Drug)	
Founded in	2002	2011/2012
Manufacturing Capacity	2 sites, 140,000L (50,000L+90,000L)	2 sites, 180,000L (30,000L+150,000L)
Approved Products	▪1 Biosimilar (Remsima) approved by FDA(2016.4)/EMA(2013.8) ▪1 Biosimilar(Herzuma) approved by Korean MFDS(2014.1)	None
Pipeline	6 Biosimilars, 3 New Antibody Drugs	6 Biosimilars
Employees	1,074(2015.12)	1,031/477(2015.12)

Source: www.celltrion.com, www.samsungbiologics.com, www.samsungbioepis.com,
https://ko.wikipedia.org/wiki/삼성바이오로직스, https://ko.wikipedia.org/wiki/삼성바이오에피스

■ CMO model suits well with Samsung's style

- Samsung is a successful fast follower with good manufacturing capability and large capital.
- Samsung is good at managing yield rate which is crucial to CMO model.

The Challenges of CMO Model



- Networking capability and horizontal cultures are needed to evolve from CMO & biosimilar company to new biologics company.
  - Networking is essential in bio-health industry.
  - Searching & screening capability is crucial: “Eyes of MIDAS” are necessary.
  - Organizational culture should be changed from hierarchical to more horizontal one.

⇒ They need New Strategy, New Organization, New Culture!

Conclusions

- Biopharmaceutical sector is a ‘touchstone’ for whether Asian emerging countries can succeed in science-based industry, which, in turn, can be evidence of being ‘developed countries’.
- The rise of **Global Innovation Network** opens a window of opportunity for Asian emerging countries in biopharmaceutical sector, as **Global Production Network** played similar roles in manufacturing sectors 30 to 50 years ago.
- There are at least 3 strategic models that biopharmaceutical firms of emerging countries can adopt: CRO, Licensing-out, CMO.
- Who will be the 1st winner tapping into **Global Innovation Network** and successfully growing into a global company? Wuxi, Hanmi, Celltrion, or else?