



Welcome to Techdow

公司简介
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一、公司基本信息

COMPANY BASIC INFORMATION

➤ **基本信息 Basic Information**

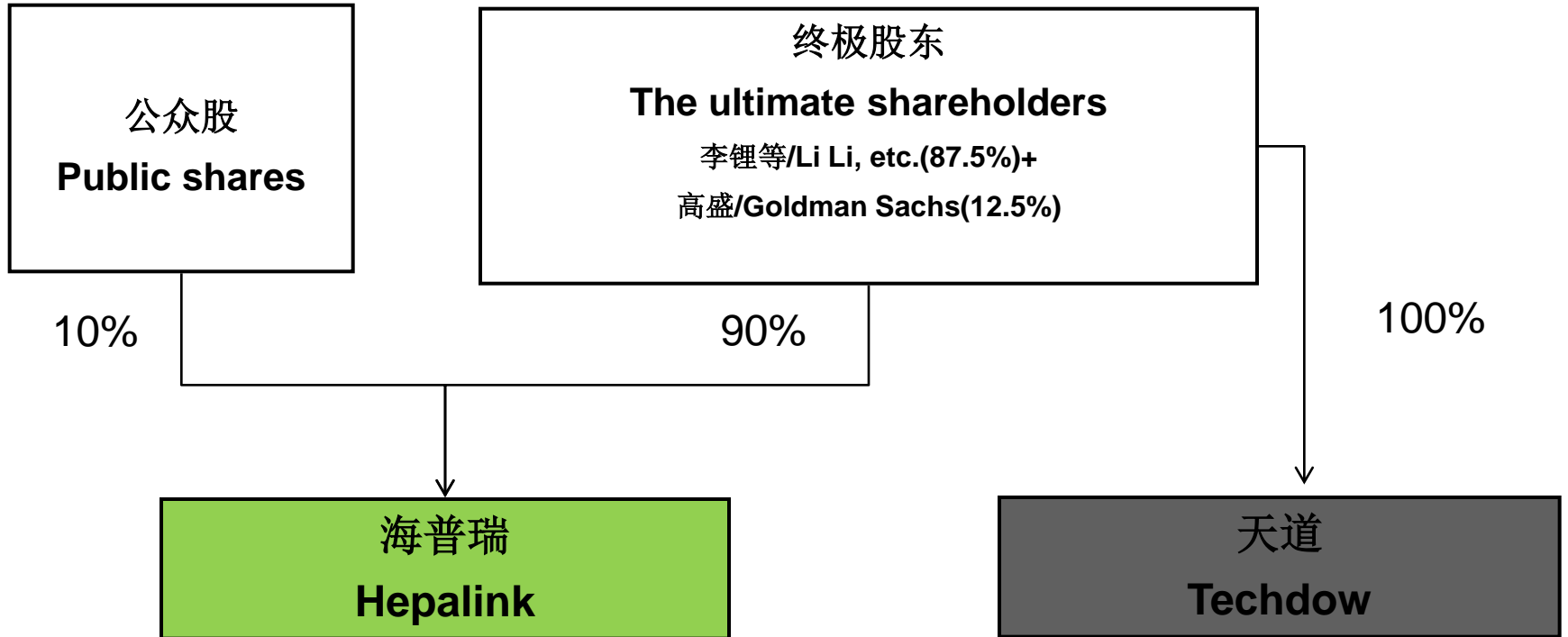
2004年6月，深圳市天道医药有限公司正式成立。

Shenzhen Techdow Pharmaceutical Co. , Ltd. was established in June 2004.

天道为专业生产低分子肝素类产品的公司，其中依诺肝素钠为我们的拳头产品。

Techdow is a professional company for manufacturing Low Molecular Weight Heparin, in which Enoxaparin Sodium is our most important product.

公司股权结构 OWNERSHIP STRUCTURE



➤ **基本信息 Basic Information**

两个第一 **Two first places in Enoxaparin field**

天道公司是中国第一家得到SFDA关于依诺肝素钠产品批文的公司。

*Techdow is **the first** Chinese manufacturer of Enoxaparin Sodium products authorized by SFDA.*

天道公司是中国第一家也是目前唯一一家通过美国FDA认证、欧盟、澳大利亚TGA、巴西 ANVISA GMP以及的依诺肝素钠生产厂家。

*Techdow is **the first** and currently the only one Chinese manufacturer of Enoxaparin Sodium products who passed US FDA ,EU, Australia TGA and Brazil ANVISA GMP inspection.*

二、公司历史及项目进程
**COMPANY HISTORY
AND PROJECT PROGRESS**

天道公司的制剂生产厂房及设备。

Techdow's facilities for enoxaparin sodium injections.





天道制剂车间产能为：制剂**2500**万支/年。

Techdow's production capacity of Enoxaparin injection : 25millions of pre-filled syringes per year.

采用最先进的德国**B+S**灌装设备，该生产线通过了中国、欧盟、澳大利亚、巴西、哥伦比亚、白俄等多国的**GMP**认证。

The production line comes from Germany B+S. The current facility passed China, EU, Australia, Brazil, Colombia, Belarus etc. GMP inspection.

天道公司新工厂：2008年大楼投入使用。

Techdow's new plant : The building was already put into use from 2008.





新工厂产能 CAPACITY OF NEW FACILITY

天道新工厂I期设计年产能为**API: 6000-8000**公斤/年;
制剂: 西林瓶**1.2**亿支, 预灌针**1.2**亿支/年。

Design capacity of Techdow's new facility in stage I:

Enoxaparin API : 6000-8000kgs

Finish products : 120 millions in vials and 120 millions in pre-filled syringes

天道新工厂II期设计年产能为**API: 10000-12000**公斤/年;
制剂: 西林瓶和/或预灌针**4**亿支/年。

Design capacity of Techdow's new facility in stage II:

Enoxaparin API :10000-12000kgs

Finish products: 400 millions in pre-filled syringes and/or vials

天道新工厂进展
PROGRESS OF NEW FACILITY OF TECHDOW

➤ 依诺肝素钠API生产线 Enoxaparin sodium production line



天道新工厂进展

PROGRESS OF NEW FACILITY OF TECHDOW

- 达肝素钠原料药生产线于**2011年9月**已经完成建设, 目前待进行工艺验证.
- 那曲肝素钙原料药生产线在规划筹备中;

- **The Dalteparin sodium production line construction was finished in Sep 2011. Now waiting for process validation.**
- **The Nadroparin Calcium production line construction is under preparation.**

三、药政历史和状态

Regulatory History and Status

天道药政状态和历史

Techdow Regulatory Status and History

08/2005	<p>首家获得中国的依诺肝素API和制剂的注册批文。</p> <p>Obtained the registration approval and became the first Chinese manufacturer of Enoxaparin Sodium API and injections approved by Chinese SFDA.</p>
03/2006	<p>获得中国SFDA的依诺肝素钠API GMP。</p> <p>Obtained the Enoxaparin sodium API GMP authorized by Chinese SFDA.</p>
09/2006	<p>获得中国SFDA的依诺肝素钠制剂GMP。</p> <p>Obtained the PFS injection GMP authorized by Chinese SFDA.</p>
06/2007	<p>依诺肝素钠API生产线通过巴西药管局的GMP检查。</p> <p>Enoxaparin sodium API production line passed the GMP site inspection by Brazil ANVISA.</p>
10/2007	<p>依诺肝素钠预灌针生产线通过哥伦比亚药管局GMP检查。</p> <p>Pre-filled syringe production line passed the GMP site inspection by Colombia INVIMA.</p>

天道药政状态和历史

Techdow Regulatory Status and History

03/2008	依诺肝素钠API和制剂生产线通过澳大利亚药管局的 GMP 检查。 Enoxaparin API and pre-filled syringe production line passed the GMP site inspection by Australia TGA .
08/2008	预灌针生产线通过巴西药管局的 GMP 检查。 Pre-filled syringe line passed the GMP site inspection by Brazil ANVISA .
11/2010	新的依诺肝素API生产线通过中国 SFDA 的 GMP 检查。 New Enoxaparin API production line passed GMP inspection by China SFDA .
06/2011	新的依诺肝素钠API生产线以 零缺陷 通过 巴西药管局 的 GMP 检查。 New Enoxaparin API production line passed Brazil ANVISA GMP inspection without any deficiency .
10/2011	成为首批通过中国新版 GMP （符合欧盟的 GMP ）再认证的依诺肝素钠制剂生产企业。 Became the first group of companies who obtained the GMP re-inspection certificate for Enoxaparin sodium injection according to the Chinese new GMP that complies with EU GMP .

天道药政状态和历史 Techdow Regulatory Status and History

03/2012	依诺肝素钠API车间以零缺陷通过了美国FDA的现场检查。 Enoxaparin API production line passed the GMP site inspection by the US FDA. with zero 483.
03/2012	预灌针车间以零缺陷通过了白俄MOH的现场检查。 Our PFS production line passed the GMP site inspection by the Belarus MOH. with zero deficiency.
02/2013	首家通过欧洲GMP现场检查，并于05/2013获得API和制剂的GMP证书。 Enoxaparin Sodium API and Injection production line passed EU GMP site inspection and obtained the certificates in May, 2013.
10/2014	依诺肝素钠API及预灌针生产线以零缺陷通过巴西药管局的GMP再认证。 Enoxaparin Sodium API and Pre-filled syringe production line passed Brazil ANVISA GMP re-inspection without any deficiency.
01/2015	依诺肝素钠API车间再次以零缺陷通过了美国FDA的现场检查。 Enoxaparin API production line re-passed the GMP site inspection by the US FDA. with zero 483.

四、产品优势

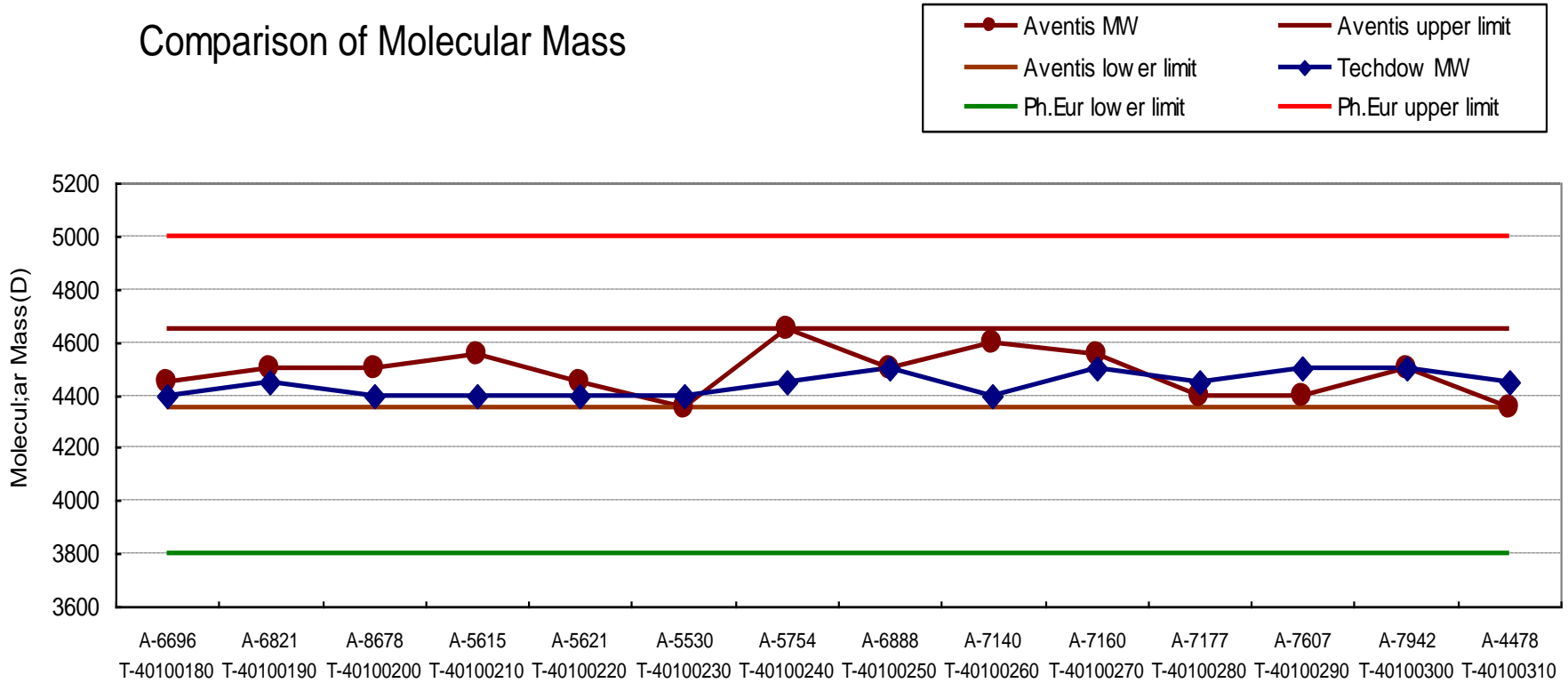
Product Advantage

天道的依诺产品与AVENTIS美国市售品质量比较

Quality Comparison of Techdow's Enoxaparin and Aventis's Enoxaparin in US market.

Manufacturer	Techdow			Sanofi-aventis (US market)		
Batch No.	401111003	401111004	401111005	1SA75	1SA36	21249
Test item						
Fxa (IU/mg)	118	118	118	117	109	119
Abs.(231nm)	232nm	232nm	232nm	232nm	232nm	232nm
MW	4452	4425	4435	4374	4375	4295
M8000	11.194%	10.965%	11.138%	10.410%	10.428%	9.688%
M2000	15.703%	15.835%	16.075%	15.798%	15.800%	16.261%
M2000-8000	73.103%	73.200%	72.787%	73.792%	73.772%	74.051%

Comparison of Molecular Mass



Remark: A-xxxx: Aventis Batch No.
T-xxxx: Techdow Batch No.



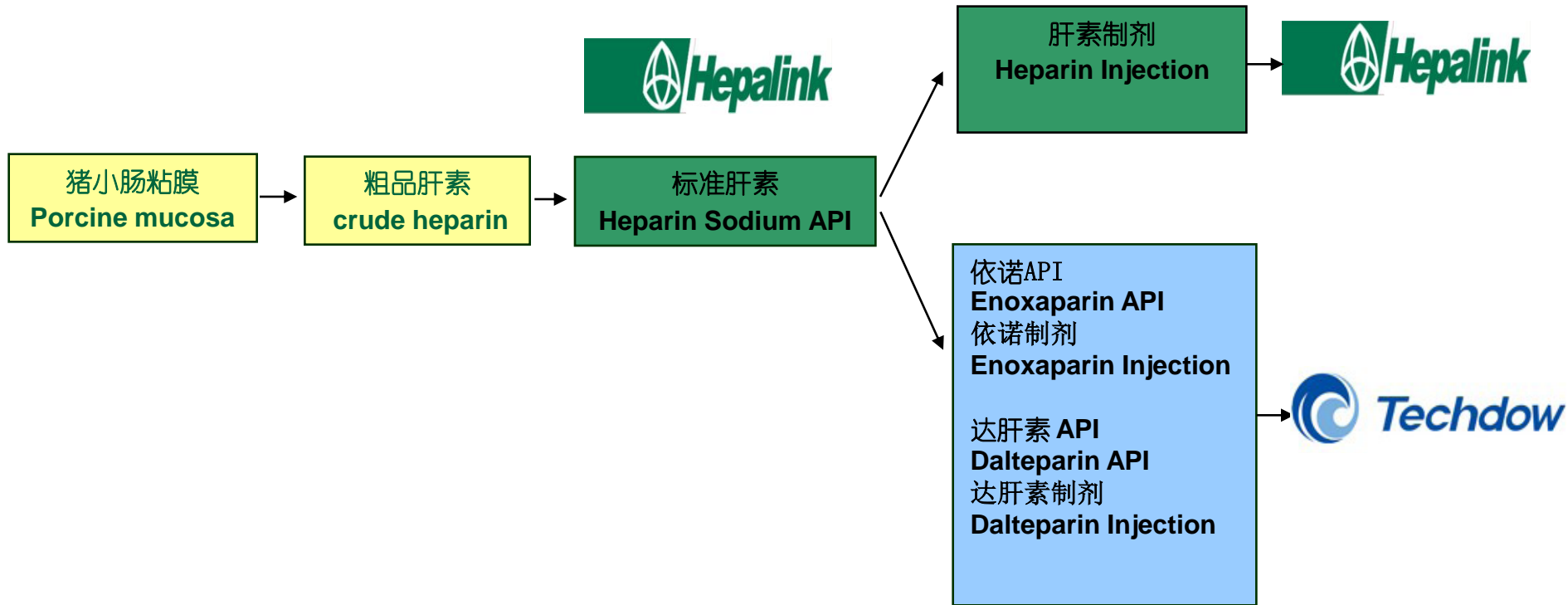
天道的依诺肝素在**20**多个国家销售已超过**8**年，从未受到过客户或者原创**Aventis**的投诉。

Enoxaparin of Techdow has been sold to over twenty countries for more than 8 years, but never receive the complains from our customers or the innovator Aventis.

独特优势

Unique Advantages

纵向产业链优势---Vertical industrial advantages



海普瑞的控制从肠衣车间开始
Hepalink's control started from Casing workshop

海普瑞的可追溯性控制 Traceability control from Hepalink

肉联厂
Slaughterhouse

肠衣车间
Casing workshop

粗品车间
Crude workshop

肝素原料药生产厂
Heparin API plant

肉联厂规模大;有驻厂检验检疫人员;只屠宰健康猪
 Large slaughterhouse; quarantine persons on site; only slaughtering healthy pigs.

只收集猪小肠粘膜
 Only extracting porcine mucosa

大规模生产;定期审计;统一工艺生产成粗品运送至深圳
 Production in large scale; Regular validation by Hepalink; Using standard process to manufacture crude heparin and then transporting to Shenzhen.

入厂的每一批粗品都有可追溯性
 Each batch of crude heparin arrived in Hepalink is traceable.



小肠
Intestines

粘膜
Mucosa

海普瑞的可追溯性控制 Traceability control from Hepalink

- 所有的猪都为食用目的养殖，注射疫苗，并经政府批准的屠场屠宰。

All pigs are vaccinated and raised for food purpose and slaughtered at slaughterhouse with approval of governmental health authorities.



1. 生猪进厂 Incoming of raw hogs

2. 政府部门检查 Authority examination

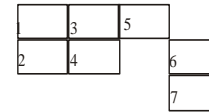
3. 技术部门检验 Technical inspection

4. 卫生处理 Hygiene disposal

5. 机械化宰猪 Mechanized slaughter

6. 卫生处理 Saitary disposal

7. 火处理 Fire disposal



海普瑞的可追溯性控制 Traceability control from Hepalink

- 小肠当场收集、就地加工，粗品有统一的工艺系统，记录完好保存，保证可追溯性。

On-site collecting and processing of intestines are made by crude heparin workshops with systematic techniques. Records for details are well made and kept for traceability.



起始原料质量可靠性 Quality assurance from the starting material

海普瑞纯品肝素25年的市场反馈：

The market response of Hepalink's Heparin Sodium API for 25 years:

- 无质量原因的退货。
Never experienced rejection due to quality issues.
- 产品的内在质量不仅适合生产肝素制剂，保持制剂良好的稳定性，其完整的结构又适合进一步生产下游产品。
High quality Heparin API not only suitable to produce Heparin sodium injection to assure the good stability of the injection, but also be qualified raw material to produce the derivative products with the intact structures.

起始原料肝素钠来源安全 *Safe source of starting material Heparin sodium*

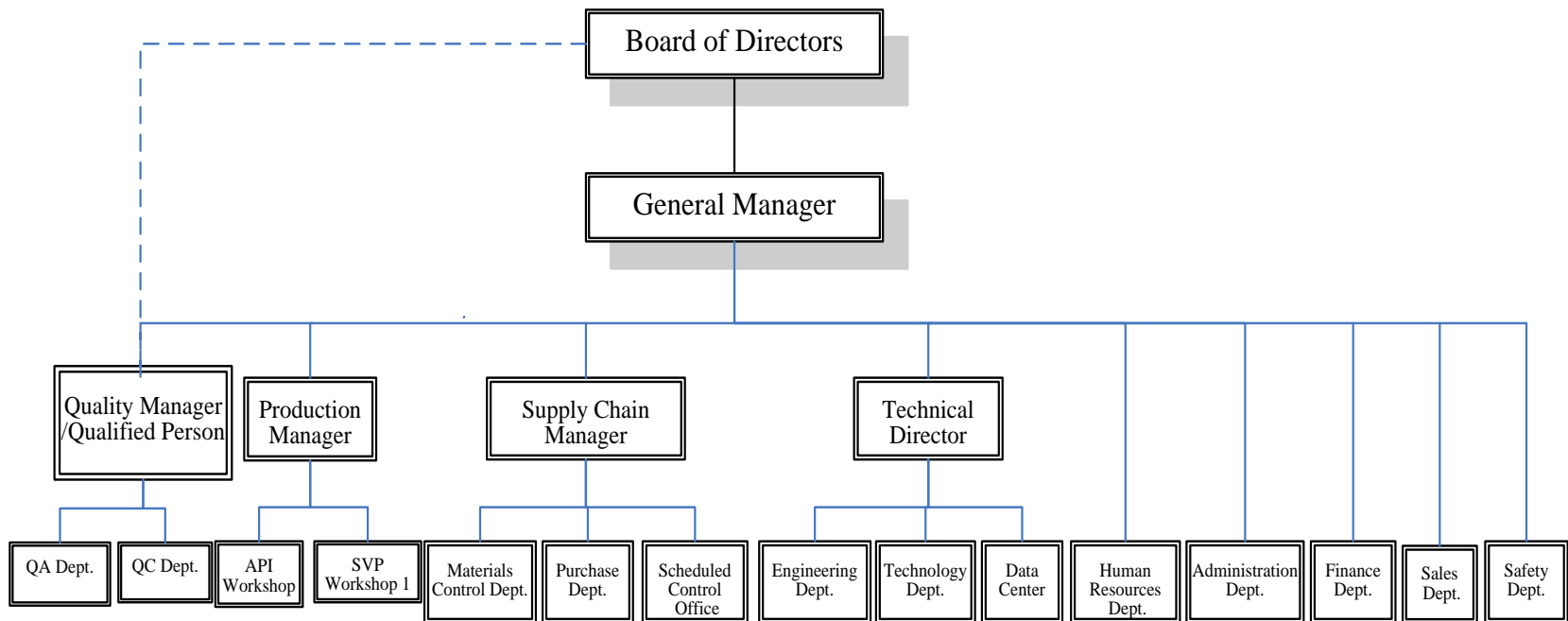
天道用来生产低分子肝素的原料－肝素钠来自于海普瑞，目前全球最大的肝素供应商。海普瑞的肝素钠已经3次零缺陷通过了美国FDA认证和欧洲的GMP认证。

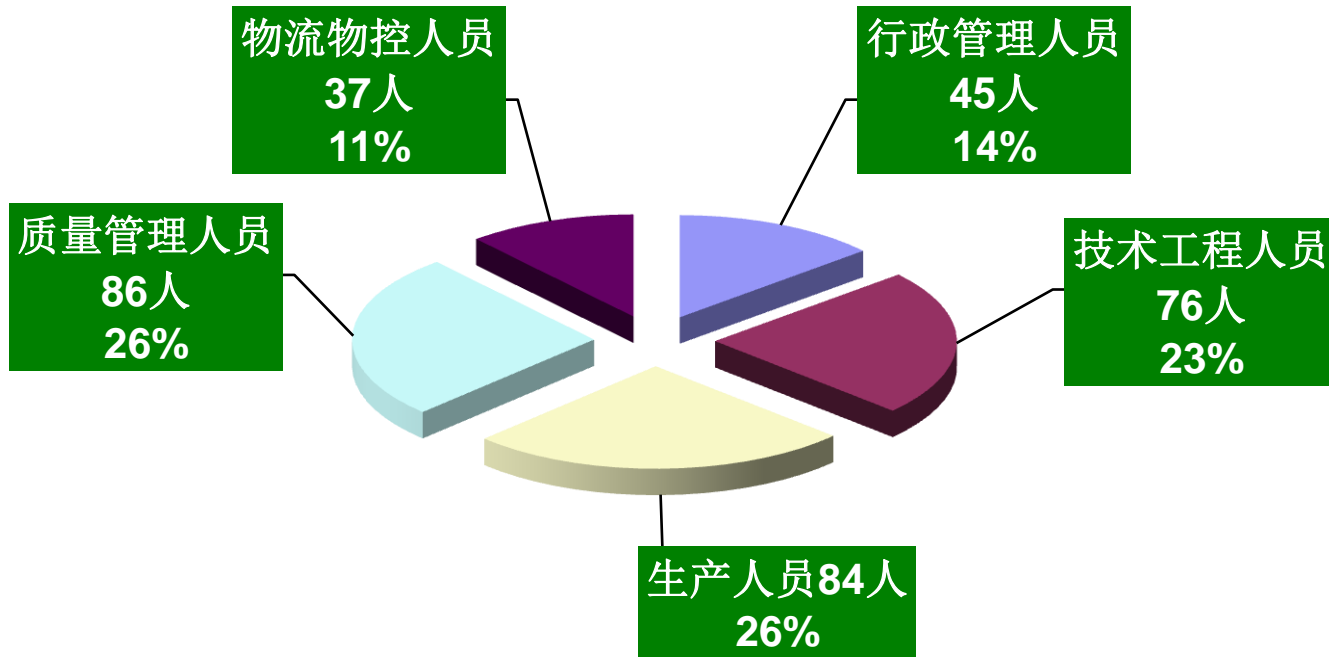
The starting material, Heparin Sodium, used by Techdow comes from Shenzhen Hepalink Pharmaceutical Co., Ltd who is the largest Heparin Sodium supplier in the world, and passed US FDA inspection without any deficiency for 3 times and EU approval.

五、组织结构和人员结构

Organization Structure and Employee Structure

公司组织结构 *Company organization structure*



员工组织结构**Employee Structure**

Quality Management:	86	26%
Storage and Distribution:	37	11%
Manufacturing:	84	26%
Technical Engineer:	76	23%
Administration:	45	14%
Total Staff:	328	

六、天道的质量理念

QUALITY PHILOSOPHY OF TECHDOW



公司教育每一位员工：也许有一天你会成为病人，你渴望用到安全有效的药品。

Our company educates each employee that one day you may become a patient, and you would be eager to use safe and effective medicines .

THANK YOU

