



The Understanding of GMP – When the East meets West

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About myself

- General Manager, Tasly Sants
- Head of Quality, TSKF (one of GSK China sites)
- Schering-Plough
 - Operational Quality Manager, responsible for API quality operations, new product introductions, global supply to US, EU, RoW
 - Quality Compliance Manager, responsible for internal, supplier and external audits, validation (SAP, new facility start up – API, Biotech, Tablet, DPI)
 - Senior Quality Supervisor for product release
 - Process Chemist, provide on line process support, GMP, assist production manager
 - R&D chemist, for API

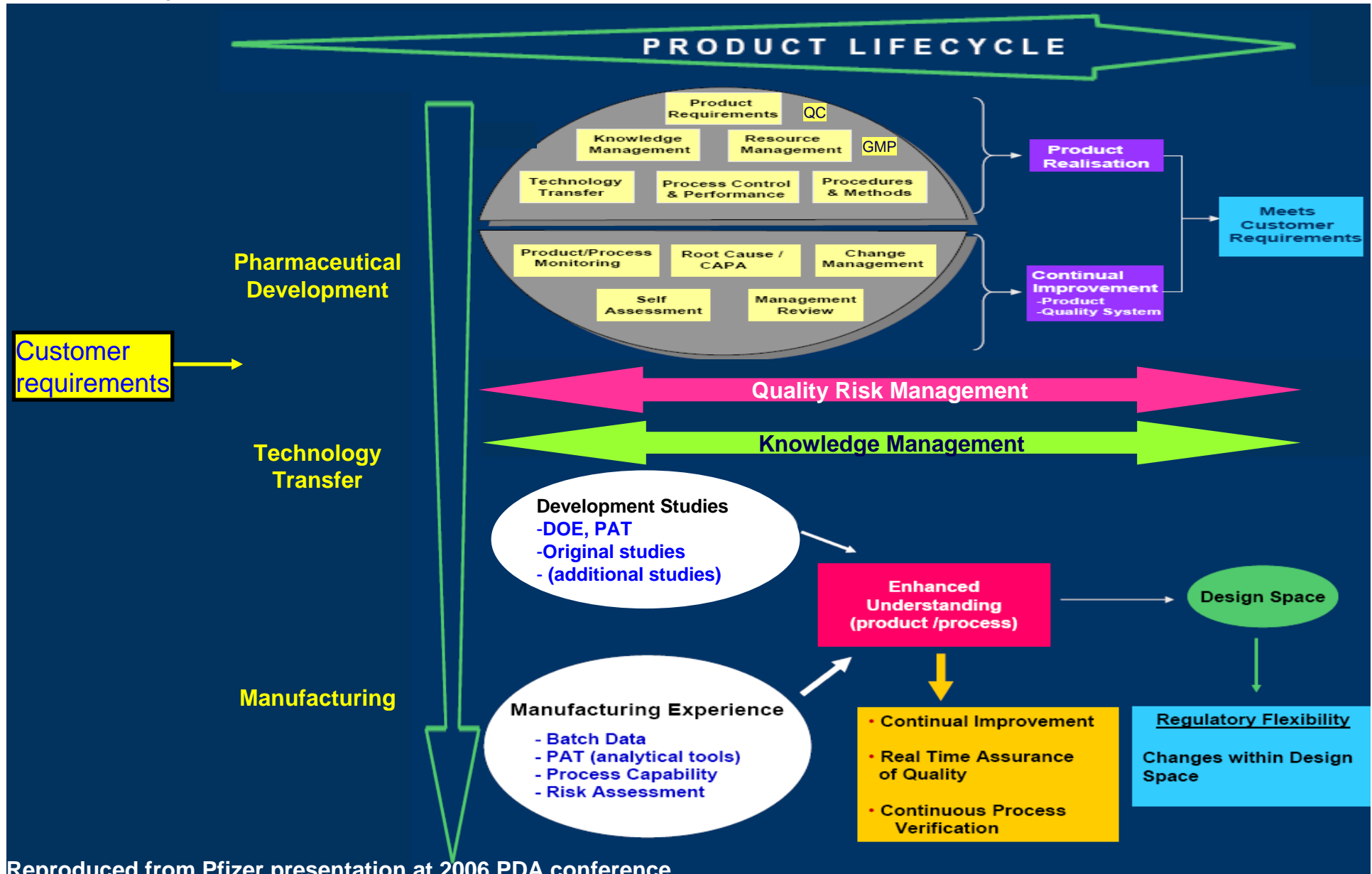


Topics to explore:

Understanding The Differences – Sustainability vs
once off

- Definition
- Management responsibilities
- Perspective on deviation, documentation
- Compliance approach
- Thinking style

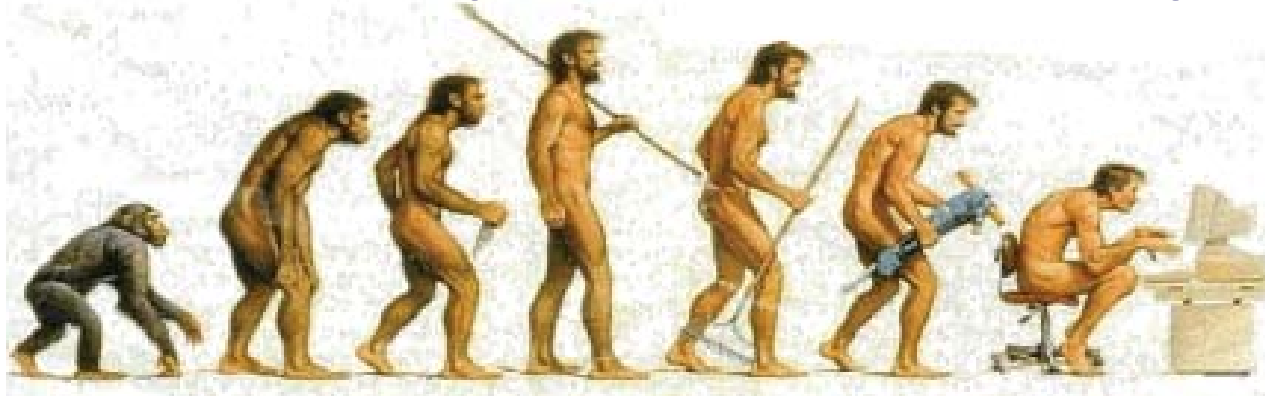
Key Concepts & Relationship



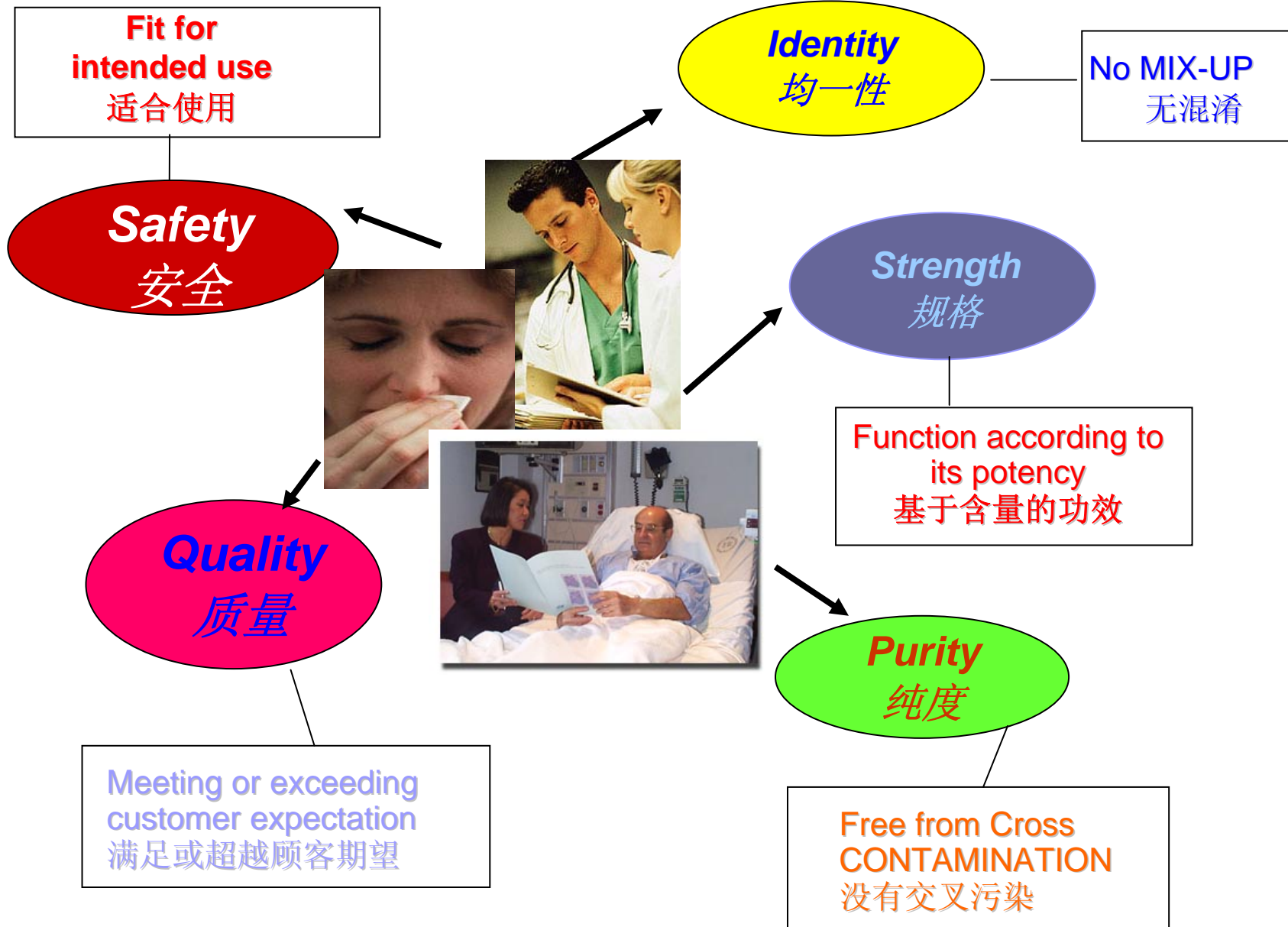
Evolution History of Quality in Pharma

- Quality Control – testing, inspection, IPC
- Quality Assurance – prevention
- Quality Management – design, develop, implement
- Quality System – integrated approach

GMP and QC is integral part of Quality Management



What is Quality ? 什么是质量?



What is Quality ? 什么是质量?

■ Definition 定义

- the totality of features and characteristics that bear on the ability of a product to satisfy fitness for use, including safety and performance.

衡量一个产品满足安全性和使用性的能力的总体特征

- A quality product is not build through inspection, but through the **system**. 好品质的产品不是检验出来的, 而是好的体系造就的结果.



Quality cannot be 'Tested In' vs QC
质量不可能是检验出来的



What is Quality System 什么是质量体系?

Build Your Quality System to Meet beyond basic regulatory requirements 建立你的质量体系而满足要求

Implementing a robust quality system can help ensure compliance with regulations related to safety, identity, strength, quality, and purity as long as the quality system addresses the **minimum** requirements of cGMP regulations as well as the needs of the manufacturer.

一个强大的质量体系的实施保证有关安全性, 质量等的法规的符合性. 质量体系解决了cGMP的最低要求, 也是生产者的需要.



- cGMP is integral part of Quality System
- Not just paper exercise
- Legal evidence of compliance, proof of integrity
- Beyond basic compliance vs just meet



The management's responsibilities

- Moral responsibility to the public
- Ensure fit for use, provide quality, safe and efficacious product
- Commitment of Senior management, supported by participation across all levels, by company's suppliers and distributors
- Effectiveness of Quality Assurance documented and monitored
- Not just about compliance
 - Visible leadership to establish and maintain company wide culture and commitment to Quality and improvement - > Sustained compliance
- Quality cannot be owned by Quality Department
 - Management is accountable



- Senior Management vs Quality Department
- Leadership, quality culture vs quality function



ICH Q10 : "Quality should be built into the product, and testing alone cannot be relied on to ensure product quality."

ICH Q10: 质量应该建立在产品中, 单纯的检验是无法保证产品质量的.

Leadership and Culture 领导力和文化

- Effective leaders shape the culture of their organizations through a powerful combination of message matched by action
有效的领导者通过身体力行建立组织的文化。
- **Ethics and Integrity** – the ability *to do the right thing* and *doing it right*.
The spirit of the law transcends the law itself.
正直- 做正确的事和正确地做事的能力。
法律的精髓在于它的精神， 远远超越它的条文本身。



Core value :

- Moral responsibility vs just a job
- Trust but verify

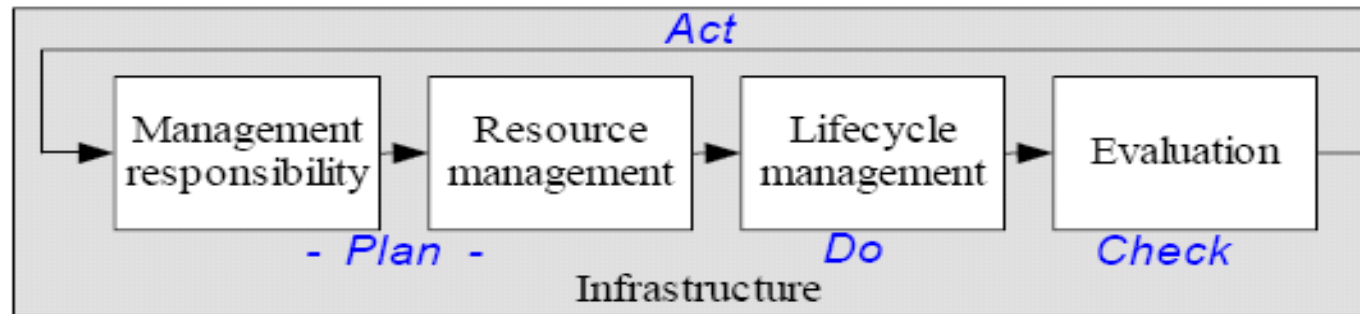




Levels of Quality Culture 质量文化的层次



Quality System Model 质量体系模式



<p>0. Quality System Infrastructure</p> <ul style="list-style-type: none"> 0.1 Define Quality System Scope 0.2 Build Quality System to Meet Requirements 0.3 Document the Quality System <p>1. Strategic Management</p> <ul style="list-style-type: none"> 1.1 Provide Leadership 1.2 Review System Effectiveness 1.3 Identify Customers and Products/Services 1.4 Establish Policies, Objectives, and Plans 1.5 Structure the Organization <p>2. Resource Management</p> <ul style="list-style-type: none"> 2.1 Develop Personnel 2.2 Purchase Materials and Services 2.3 Control Outsourced Work 2.4 Supply and Maintain Equipment 2.5 Provide Support Services 	<p>3. Lifecycle Management</p> <ul style="list-style-type: none"> 3.1 Plan Work 3.2 Design New Products, Services, Processes 3.3 Accept Work 3.4 Perform Work under Controlled Conditions 3.5 Detect Problems before Product/Service Release <p>4. Quality System Evaluation</p> <ul style="list-style-type: none"> 4.1 Monitor and Measure Selected Metrics 4.2 Work through Problems 4.3 Analyze Data for Trends 4.4 Assess Consequences 4.5 Conduct Audits 4.6 Address Recurring Problems 4.7 Anticipate Problems 4.8 Promote Improvement
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Lifecycle approach



Product & process design and development

Define desired product performance upfront; identify product CQAs

Design formulation and process to meet product CQAs

Continually monitor and update process to assure consistent quality

Identify and control sources of variability in material and process

Understand impact of material attributes and process parameters on product CQAs

Risk assessment and risk control

Quality System Model 质量系统模型

- Specifically, successful quality systems share the following characteristics: 成功的质量体系有以下特征:
 - Science-based approaches 以科学为基础的方式
 - Decisions based on an understanding of the intended use of a product 决策基于对产品用途的充分理解
 - Proper identification and control of areas of potential process weakness 适当地识别和控制可能的过程弱点
 - Responsive deviation and investigation systems that lead to timely remediation 有效的偏差和调查系统保证及时的恢复措施.
 - Sound methods for assessing and reducing risk 有效的方法评估和降低风险
 - Well-defined processes and products, starting from development and extending throughout the product life cycle
从研发到产品的整个生命周期中贯穿良好定义的过程和产品.
 - Systems for careful analysis of product quality 产品质量的化验系统
 - Supportive management (philosophically and financially) 支持性管理



- Systematic, logical, holistic approach vs adhoc
- In depth problem analysis vs surface patching
- SOP is in place and in use vs SOP is for show
- Data based evidence and facts vs experience, gut feel
- Sustained compliance vs just get NDA approval

Level 5 Quality Culture 第5级 质量文化



- In a robust, modern quality system as described in ICH Q10 will demonstrate : ICH Q10 指出强大的现代的质量体系能够证明:
 - commitment by Senior Management 高层管理层的承诺
 - aligning quality system plans with the manufacturer's strategic plans 质量计划和生产计划同步
 - managers should demonstrate strong and visible support for the quality system 经理层有强大的可见的对质量体系的支持
 - global implementation throughout the organization (e.g., across multiple sites). 全球组织内的实施
 - Active internal communication on issues that may affect quality at all levels 在所有层面的有关质量问题的内部有效沟通.
 - Effective integration of Quality systems staff into manufacturing activities 质量体系有效地和生产活动相结合.
 - Promotes improvement 推动改进
- When fully developed and effectively managed, a quality system will lead to consistent, predictable processes that ensure that pharmaceuticals are safe, effective, and available for the consumer. 当一个质量体系完全建立和有效地管理时, 一个持续的可预见的流程会保证药品对消费者会是安全有效和可得到的.



Summary

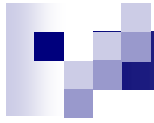
The difference -

- quality cannot be tested into
- Senior Management responsibilities vs Quality Department
- Legal evidence vs just paper record
- Data driven, evidence based fact vs gut feel. Understand the why is important.
- Systematic and holistic vs sporadic / adhoc
- Sustained compliance approach vs just meet standards
- Moral responsibility vs just a job
- Sustainability is key



Reference Websites

- www.ich.org
- <http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev4.htm>



THANK YOU !