藥廠組織溝通與協調之團隊合作經驗分享—以製劑廠為例

杏輝醫藥集團 SINPHAR GROUP

財團法人2016藥廠品質管理人員訓練課程系列(三)

盧蘊澤 博士

宜蘭廠務辦公室 總經理(副總)

07/21/2016

個人簡歷

- 201506 ~: 宜蘭廠務總經理(副總)
- 2012 : 董事長室風險暨技術管理組特別助理
  兼研發中心總監(資深協理)
  癌症注射劑工廠專案召集人
- 2011 : 品質領導組資深協理(兼任品保處)
- 2010 : 總經理特助
- 2009 : 研發中心協理
  兼任董事長室品質領導組副召集人
  測試實驗室主管
- 2008 : 總經理辦公室特助
- 1998 : 研發處經理
- 1997 : 杏輝藥品 品保部經理
- 1993~1996: DCB 副研究員(環生專案)

大綱

- GMP要求下的組織溝通與協調
  “以QP的角色解讀”
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  “以PM的角色分享團隊分工的組織運作”

杏輝藥品工業股份有限公司簡介

- 設立日期：1977 年 7 月 2 日(39年)
- 董 事 長：李　志　文
- 總 經 理：白　友　烺

- 員工人數：全公司 801人/工廠 618人（05/31/2016）
- 總公司、工廠：宜蘭縣冬山鄉中山村 84 號

公司簡介(沿革)

年份	GMP system
1988	通過衛生署 GMP 查核
2004	通過衛生署 cGMP 查核
2011	通過衛生署 PIC/S GMP 查核（三月全廠性，十月加入軟膠囊）
2013	通過食品藥物管理署 PIC/S GMP 後續查核（效期至 2016/05/14）
2015	食品藥物管理署 PIC/S GMP 通過高致敏固型劑廠房(錠劑、膠囊)、癌症注射劑
年份	ISO system
1997	通過標檢局 ISO-9001 品質系統查核
2004	實驗室通過 TAF ISO-17025 品質系統查核
2005	通過標檢局 ISO-14001 環境管理系統查核
2009	通過 OHSAS 18001 職業安全衛生管理系統
年份	國外查核
2009	通過日本 PMDA 核准無菌製劑點眼劑(certified no.5122607000052)
2014	通過日本 PMDA 核准高致敏製劑固型劑(certified no. 5122507044277. 512607026266)
2015	通過日本 PMDA 核准無菌注射劑(certified no. 5122708005064. 5122708005065)

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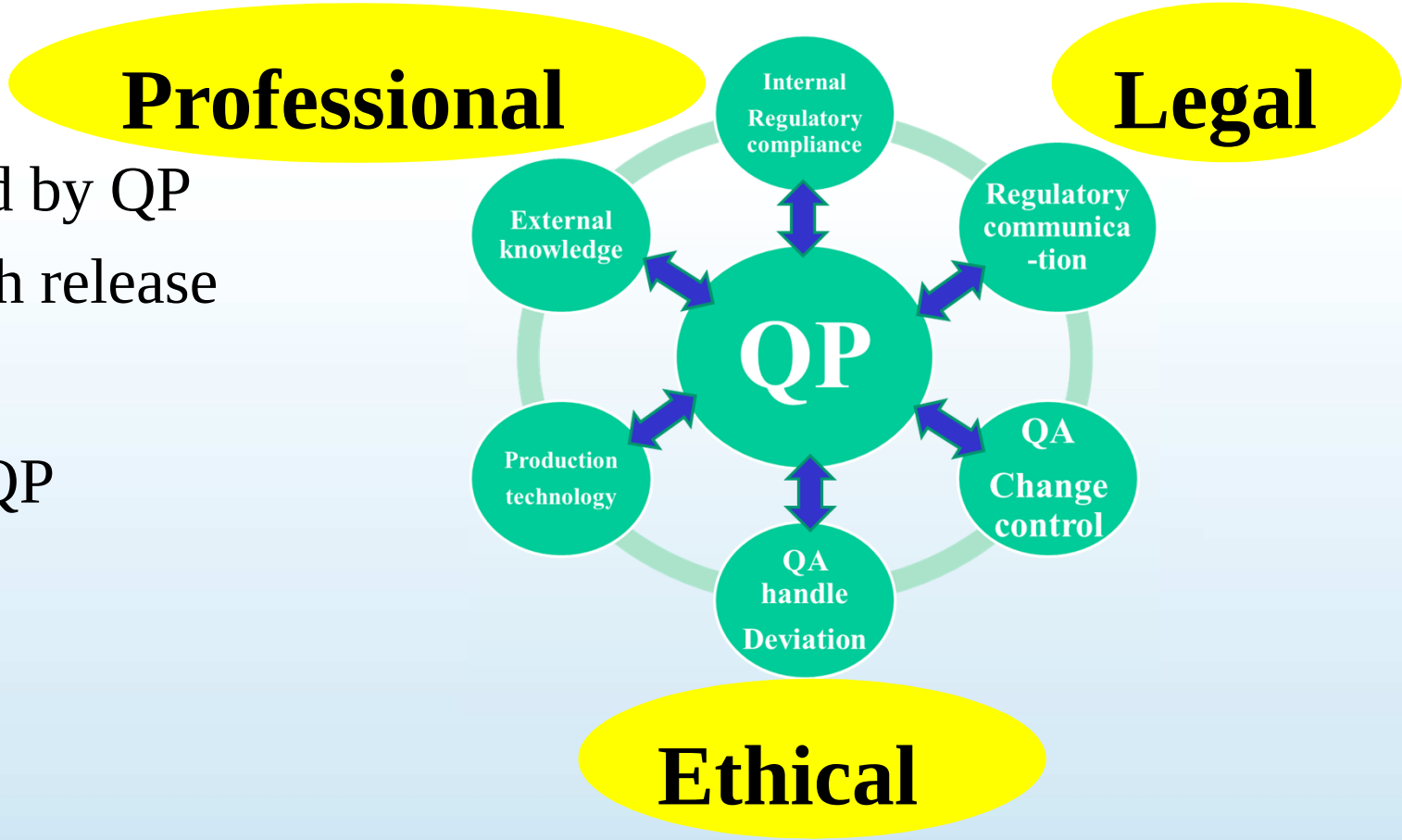
Legal Duties of QP

Defined in EU Directive 2001/82/83 (market product)
EU Directive2001/20 (IMP)

- Certification
  - Must be performed by QP
  - Must precede batch release
- Release
  - Need not be by a QP



Routine duties of a QP

- Compliance with the Marketing Authorization
- Compliance with GMP
- Manufacturing and testing processes validated
- Deviations and changes approved and additional samples tested (if necessary)
- Checks and tests performed
- Documents completed and endorsed
- Audits carried out
- ALL relevant factors considered

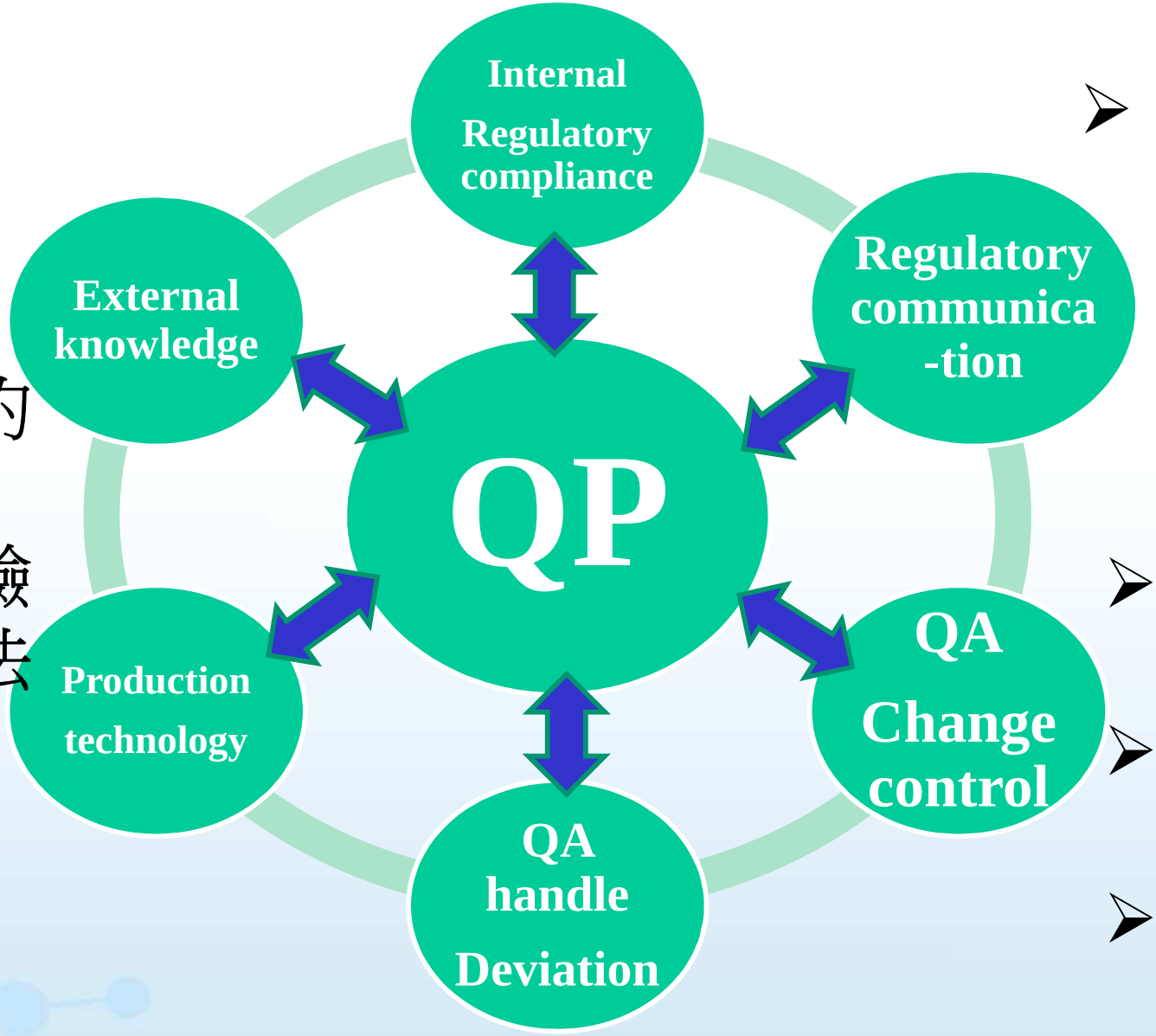
Routine duties of a QP

- Applies equally to Intermediate AND to the final QP (unless otherwise agreed in technical contract)
- The QP is required to maintain knowledge and experience... scientific progress AND Quality Management
- If the QP is not familiar with processing/products... must first ensure that he/she has first gained the relevant knowledge

RAC -- interface

- Communicate and negotiate with regulatory authorities to facilitate compliance on regulated products.
- Coordinate company presentations to regulatory advisory committees/.. to facilitate regulatory compliance.
- Provide input on proposed legislation, regulations, guidelines, … to ensure consistent and clear application of requirements.
- Review public communications, press releases
- Participate in internal product review committees (labeling, quality, launch)
- Develop early warning systems to identify potential regulatory compliance issues affecting the company and advise affected internal functional groups

- 累積足夠的經驗值
- 工業的經驗
- 參與外部法規活動



- 以病人為優先
- 協助公司理解法規要求

- 參與系統運作
- 對系統運作的信心
- 平衡公司經營壓力

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ISO 9001:2015 says about “communications”

- 5. Leadership>>Requirement of **top management** leadership
  5.1.1 c) ensuring that the quality policy is communicated, understood and applied within the organization
  5.1.1 g) communicating the importance of effective quality management and of conforming to the quality management system requirements.
- 7.4 Communication>>The organization shall determine the internal and external communications relevant to the quality management system (what, when, whom, how)
- 8.2.1 Customer Communication (外部與內部客戶)
  - Information relating to products and services;
  - Enquiries, contracts or order handling, including changes;
  - Obtaining customer views and perceptions, including customer complaints;
  - The handling or treatment of customer property, if applicable;
  - Specific requirements for contingency actions, when relevant
- 8.4.3 information for external providers (生產製造原物料，檢驗測試，運送…)
  The organization shall ensure the adequate of specified requirements prior to their communication to the external provider.

本次修訂取消”品質代表”，而是以**Top Management**全權負責

PIC/S GMP要求的組織溝通

- 1.5. & Glossary
  - Quality risk management – a systematic process for the assessment, control, ***communication*** and review of risks to the quality of the drug (medicinal) product across the product lifecycle
- Annex 20
  - 4.5. Risk communication is the sharing of information about risk and risk management between the decision makers and others
  - Communications might include those among interested parties; e.g., regulators, and industry, industry and the patients, within a company, industry or regulatory authority, etc.

Top management

one or more than one person

外部要求

authorization

Quality policy

Reflect in Design to manufacture and sale during product life cycle

What , who, when, how

By

SOP, training, audit, routine review,

knowledge base review, reporting system

Quality manage ment

resource

供應鏈

4.1 understand the organization and its context

External issues

- Legal, technology, competitive, market
- Cultural, social, international

***Nokia:* 我們做錯了什麼?**

Internal issues

- Value, culture, knowledge
- Performance of the organization

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PIC/S GMP Chapter One

- The holder of a manufacturing authorisation must manufacture medicinal products so as to ensure that they are fit for their intended use, comply with the requirements of the Marketing Authorisation and do not place patients at risk due to inadequate safety, quality or efficacy.
- The attainment of this quality objective is the **responsibility** of **senior management** and requires the participation and commitment by staff in many different departments and at all levels within the company, by the company's suppliers and by the distributors

Tasks by system of quality assurance

- Design and development acc. to GMP **(研發)**
- Production and control operation acc. to GMP **(生產)**
- Managerial responsibilities **(組織，流程設計)**
- Supply and use of correct starting material **(採購，QC)**
- Controls/validation (intermediate product) **(生產)**
- Finished products, processed and checked **(生產，QC)**
- Product release acc. to market authorization **(RA)**
- Store, distribution and handled **(運銷)**
- Self inspection, quality audit **(稽核)**

RD

- 產品主檔，Design space

技轉說明會

生產

- 製造場所，設備校正，驗證

工程企劃／確效
Task force

採購

- 規格，供應商評估

供應商稽核
異常檢討
變更管制
風險管理

QC

- 規格，放行

實驗室稽核
異常檢討
變更管制
風險管理

生產

- 製造管制

線上稽核
批次審查
異常檢討
變更管制
風險管理

QC

倉儲

留樣，安定性計畫
模擬回收，召回，客訴調查

QA人的特質

- ✓ 聯想
  - **Why and why not**
- ✓ 好奇 **(5 why)**
- ✓ 推理 **(cause/fact)**
- ✓ 好的記憶力

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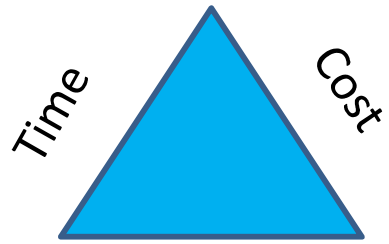
Overall project phases

Initiation → Planning → Execution → monitoring → controlling → closing

Key elements of a project >> S,Q,C,T…

- Scope: setup “deliverables” ”work package” “WBS” “Risk analysis”
- Quality[$scope, quality$]
- Cost
- Time
- Risk
- Resources



Scope, quality

Stakeholder利害關係人

- Definition: who will be interest on the project
  - Sponsor
  - Who will benefit from the project
  - Related departments being effected or benefit by this project
- Can exert power and interest on this project
  - Key stakeholder >> high power and high interest level
- Strategies for gaining support or reducing obstacles
  - Periodic meetings, status update, get their input

Building a cytotoxic Injectable plant

Injectable cytotoxic plant: supply for Japan market

Product list (possible expansion)

Cost estimate

Target date

Building: know your process

- Space for production – machine, material flow
- Space for entry and exit – personnel flow
- Space for supporting system
- Space for storage
- Pest control & hazard handling
- Air handling & BMS system + UPS + power supply
- Exhaust air/water management

Machines: know your process

- Vial washer + tunnel oven
- Filling & capping & external washer
- Filling isolators + VHP
- Autoclave
- Compounding Isolator
- Compounding tank + Buffer tank
- Pure steam & Water systems
- CAD/N2/instrument air

Roles of the Project Manager

- Build a team and assign the jobs
- Scheduling (time) and budget (cost)
- Monitoring schedule and give timely reports
- Monitor the quality of contractors/subcontractors
- Monitor financial progress
- Communication
- Take control actions – foresees the needs
- Crashing the project
- Rewards to the team
- Write the close report

Assembly team members

- Assigning/recruiting team members
  - “responsible”, “accountable”, “consult”, “inform”
  - Never let only one person knows the tasks
- Working with functional managers (正式的組織主管)
- Kick off meeting (包含所有的參與者)
  - Clarify the project mission, deliverables
  - Responsibility assignment matrix
- PM as the greatest resource
  - Problem solving
  - Listen to the problem
  - Allocate time for member units
  - PM also needs assistant (backup)

How to be “win-win” in the project

to stakeholders, team members, contractors

- Accept the authorities, do not fight >> role No.1
- Remove negative emotion >> never be the same
- Ask for advise and listen >> seek supports
- Be tactful and honest >> 說到做到 very import
- Make them feel good >> add values in team work
- Tailor your communication to gain support
- Add key members when necessary >> technical or management, co- with replaced team members

CONCLUSION

How to communicate?

- Suggest reading
  - *The 7 habits of highly effective people*
    - Paradigm shift
    - “Sharpen your saw”
      - Take time to recharge yourself
    - “Be proactive” an take control of you life
    - “Begin with the end in mind”
    - “Put first things first”-priorities
    - “Win-win” vs “Lose-Lose”
    - “Seek first to understand, than to be understood”
    - “Synergize” ~ openness & respect

How to communicate?

- Suggest reading
  - *A whole new mind (the right brain thinking)*
    - Design ~ utilize with significance >>Know how to tell story
    - Symphony ~ put things together is better than take thing apart i.e. Velcro
    - Empathy ~ learn to read facial expression, a universal language
    - Work with play

Thank you for your attention!

杏輝天力(杭州)藥業有限公司
Sinphar Tian-Li (Hangzhou) Pharm.Co., Ltd.

中加康普製藥股份有限公司
CanCap Pharmaceutical Ltd.

和田天力沙生藥物開發有限責任公司
Hetian Tian-Li Pharmaceutical Development Co., Ltd.

杏力醫療器材生技股份有限公司
ZuniMed Biotech Co., Ltd.

杏輝醫藥集團人才訓練中心
Sinphar Group HR Training Center

杏輝醫藥集團研發中心
Sinphar Group R&D Center

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SynCore Biotechnology Co., Ltd.