European QP Forum 2013
Lisbon

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Summary & Key Messages

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Pre-Conference Work-Shop: „The Role of the QP in a global System in a multinational Company“

- „Quality Culture“: Quality is everyone‘s responsibility!
- Behaviour not SOPs!
- Deviations at CMO should be communicated to final release QP (at least any deviation more than minor)
- „QP needs to be convinced prior to release, in doubt -> reject“

EQPA:

- **Plan to provide tool box for QPs (Checklists, decision trees, etc.) in 2014**
- **„QP sits between industry and patients with good relationship to the regulators“**
- **QP is responsible for supply chain traceability (regardless of its complexity)**

- **Talk to other QPs (if you are unsure, need help, are under pressure, …)**
- **Be prepared, keep an open mind, listen, assess, discuss and then make a decision**
- **But remember, patient safety should never be compromised and science does not override compliance**

New Chapter 7 of EU-GMP-Guide (Outsourced Activities):

- This includes not only production, testing, validation, calibration, etc. but also e.g. artwork, washing of packaging material, archiving of GMP-documents, etc.
- Contract needed with all levels (including „minor“ risk)
- *„7.8 Contract Giver … responsible for reviewing and assessing the records and the results related to the outsourced activities.“* -> BRR ?
- QP to visit mfg. process, understand processes and Q-Systems
- EU-site/QP should audit upstream-site (even if under the same Corporate Q-System) or audit the Corporate Auditing group or participate in Corp. Audits to ensure appropriate consideration of EU-regulations (observations received in NL, Germany, …)
  - Corp. Audits make audit reports available to final QP
  - Corp. Audit group to notify final QP in case of obs. >minor
  - Corp. Audit group to ask downstream QP(s) prior to audit planning

- Risk Assessment for appropriate level of GMP for excipients (Draft guidance, comments until 30 April, 2013)

- Ph. Eur.
  - Knowledge database for EP-monographs available online
  - CEP-inspections: about 20-40 % lead to withdrawal of CEP
  - EDQM also monitors FDA-WL to assess potential withdrawal of CEP
  - ISO-Standard for secondary reference standards under development

- Good Distribution Practice (GDP)
  - Returned goods from third country, falsified, expired, recalled or rejected products -> segregated storage required (validated IT not sufficient)

Main roles of a QP include also:

- Tell Senior Management about new requirements and responsibilities and consequences of not implementing them
- Provide input in building Q-Systems
- Ongoing reliance by attending QMR and other meetings, approving APQR, …
- Receive notifications of audits (any observations > minor)
- Request comprehensive diagram to illustrate supply chain
- Sign QP-declaration

What makes a good QP?

- Technical skills
  - Academic qualification
  - Understanding of GMP
  - Understanding legal requirements
  - Practical experience in pharmaceutical industry

- Non-technical skills
  - Communication skills
  - Interpersonal skills
  - Problem solving
  - Decision making

QP = Adding value to the business!

QP must:

- Consider cost implications as well as quality, make sure not to compromise quality
- Maintain his/her independence
- QP is employed to make decision on „grey areas“
- Work with the business team to solve problems, not to create new ones
- Get involved in new products, facilities design early on in the project