Data Integrity from a Qualified Person's Perspective

Pharma Congress 2019/Data Integrity
9-10 April 2019
Düsseldorf/Neuss, Germany
(modified)

ECA Academy
Your GMP/GDP Information Source

Contents

Reference: NSAI Certification

- **A regulatory pillar snapshot**
- The Qualified Person's "data" challenge
- Making data integrity integral to a Qualified Person's daily work

Regulatory Framework & Data Integrity

Data integrity – EU GMP requirements

- EU GMP Eudralex Volume 4, Chapter 4: Documentation
  Annex 11: Computerised Systems
  Annex 15: Qualification and Validation

Data integrity – FDA cGMP requirements

- 21 CFR Part 11, Electronic records, electronic signatures
- 21 CFR 211 Requirements for laboratory records: complete data
- FDA Draft Guidance for Industry ‘Data Integrity and Compliance with cGMP’

Data Integrity References and Further Reading

- European Compliance Academy (ECA), GMP News 22/06/2016,
- ICH Q9, ICH Harmonized Tripartite Guideline, Quality Risk Management,
- ISPE GAMP 5. A Risk-Based Approach to Compliant Computerized Systems
- MHRA GMP Data Integrity Definitions and Guidance for Industry March 2015
- MHRA GxP Data Integrity Definitions and Guidance for Industry, Draft
- version for consultation, July 2016
- PIC/S, Draft Guidance, PI 041-1 (Draft 2), Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments.
- WHO Technical Report Series 996 Annex 5, Guidance on good data and record management practices (May 2016

The Legal Basis for a Qualified Person (QP)

- EU Directive 2001/83/EC (human medicinal products)
- EU Directive 2001/82/EC (veterinary medicinal products)
- EU Directive 2003/94/EC (GMP for medicinal products for human use)
- EU GMP Guide (Parts I, II, III and IV) and its Annexes (1-19)
- EU GMP EudraLex Volume 4, Annex 16: Certification by a Qualified Person and Batch Release ("**The QP's Bible**")

Main Responsibilities of MAH and QP within GMP

The Manufacturing Authorisation Holder (**MAH**) is responsible for the

- Quality,
- Safety
- and Efficacy

of a medicinal product over its lifetime.

The **MAH** has to enable the **QP** to carry out their duties

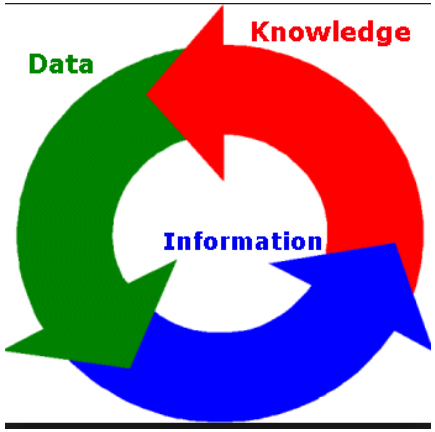
QP has to certify each batch of a medicinal product to be suitable for release

- for sale or
- for use in a clinical trial,

is named on the Manufacturer's Authorisation (MA)

The responsibilities of a QP may be delegated, but only to another QP!

Content



- The regulatory pillar snapshot
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Clarity on the Batch Release Process

Annex 16 of the EU GMP Guide clearly **defines the batch release process** and the **data needed** by a QP.

The process is comprised of 3 steps:

- Compliance check on batch manufacturing and testing
- Batch certification by the QP
- "Released" status assigned to the product

QP Certification Details

QP must certify each batch within the EU before

- Release for sale
- Supply in the EU
- Export

QP Certification is permitted under the terms of the

- Manufacturing license
- MIA (Manufacturing & Importation Authorisation) license
- Certification is recorded in a register or equivalent document

QP Certification and Batch Release

- In Annex 16, many additional responsibilities are listed which need to be ensured by the QP
- The **work can be delegated** if the QP can rely on a Quality Management System
- QP should have **on-going assurance** that **this reliance is well founded**

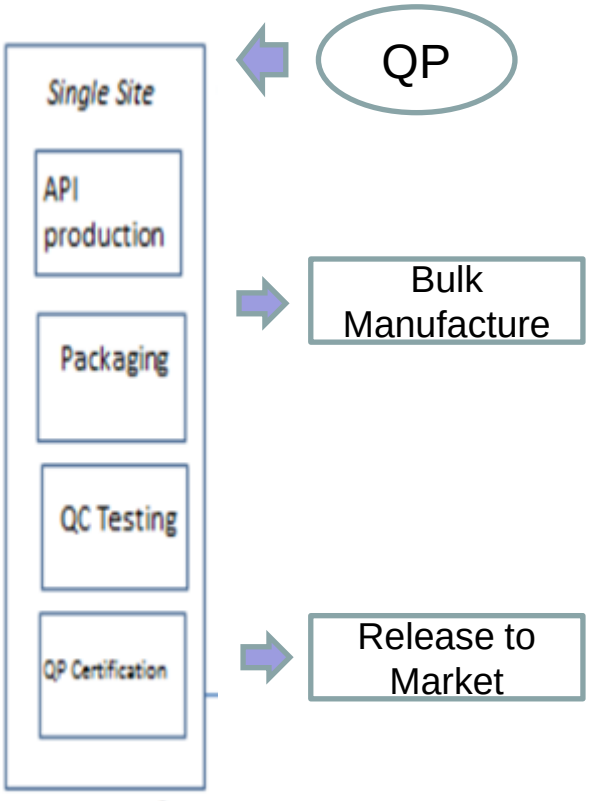
Annex 16 Key Requirements Concerning Release Certification

Amongst these "Tasks" are:

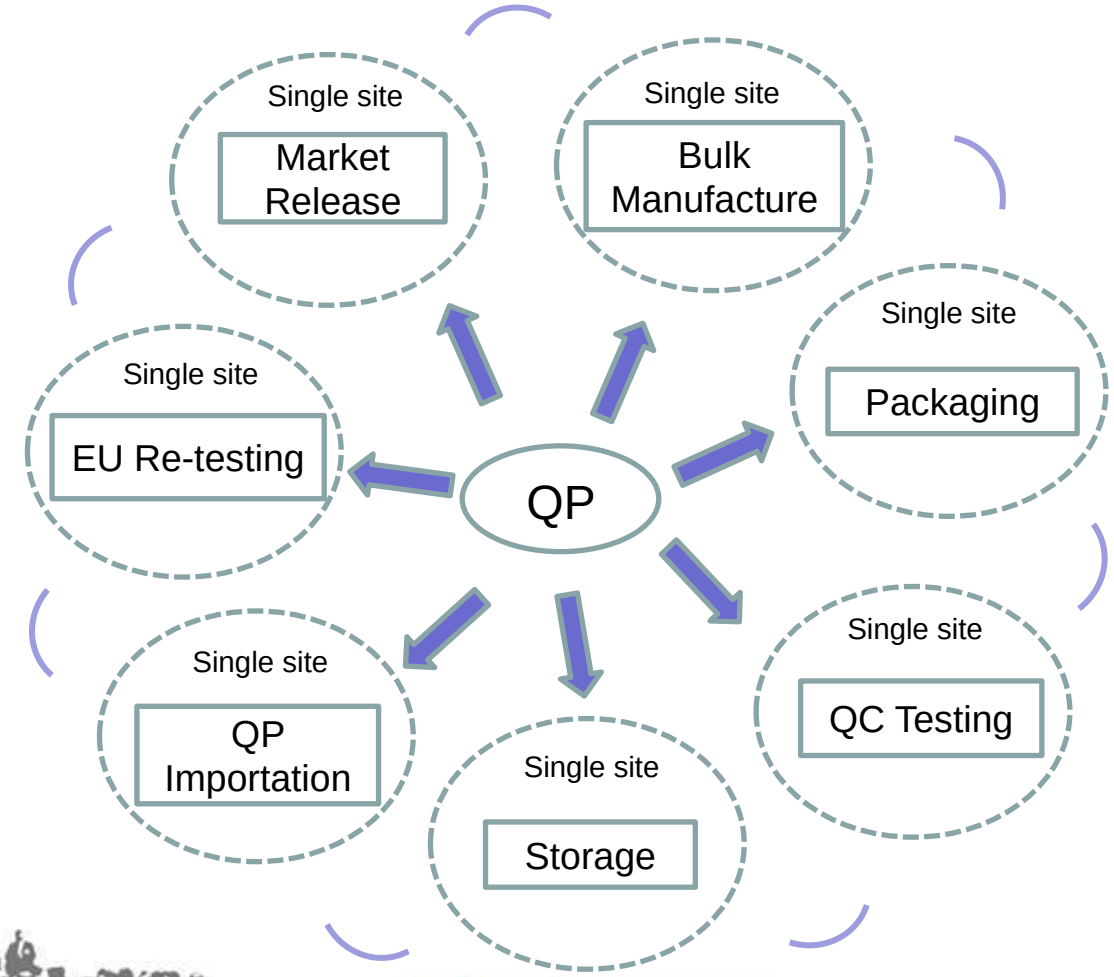
- Starting materials comply
- **Supply chain** is secured, including GMP assessments by third parties
- Necessary audits performed and **audit** reports are available
- **Manufacturing** and **testing** performance are compliant with MA
- Manufacturing and testing processes are validated
- **Changes** evaluated and investigations completed

Supply Chain – Qualification

as it was



as it is today



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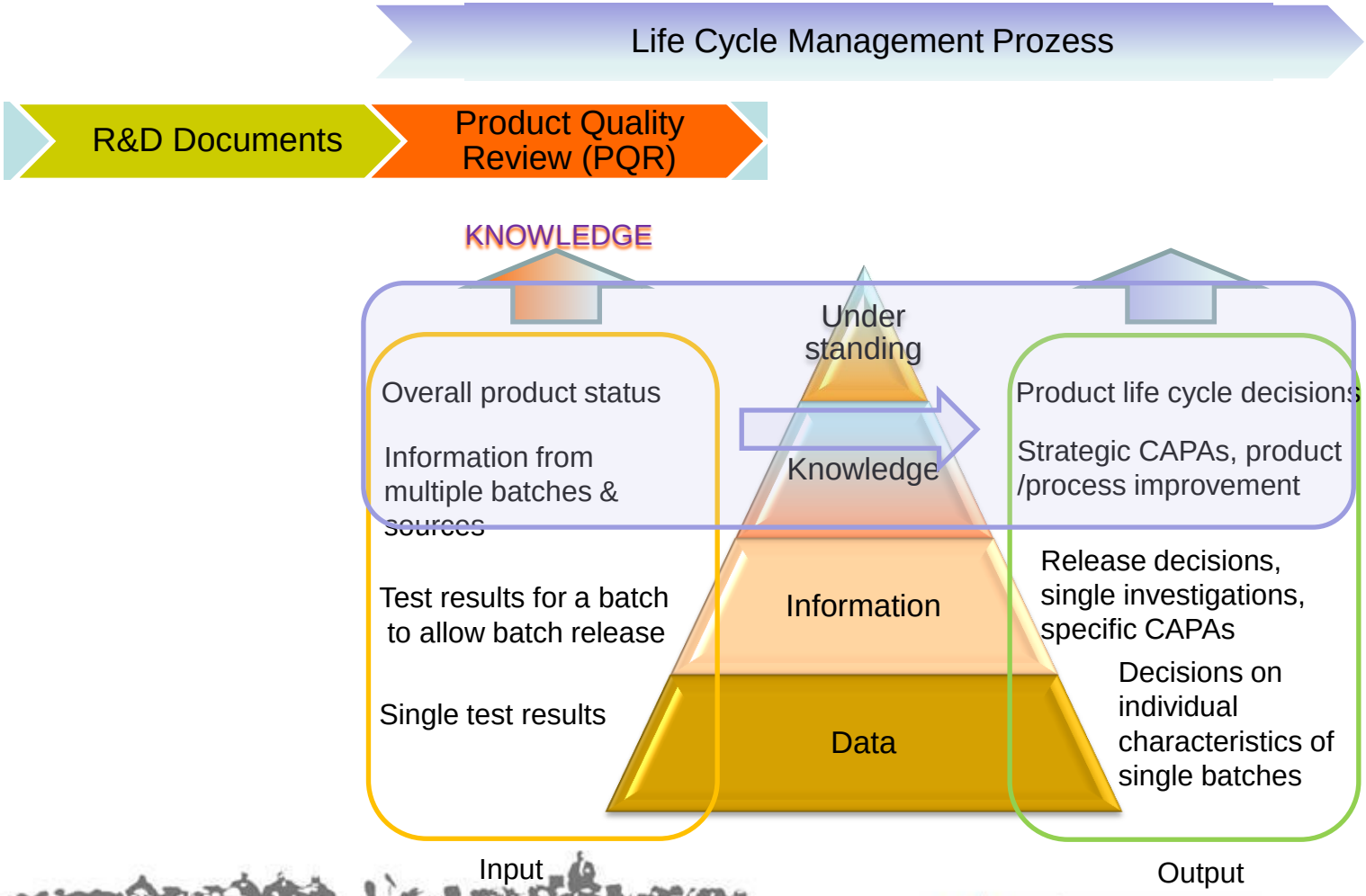
Reference: European QP Association

How do all GMP documents/data relate?



Daily Data Integrity Impact on the Qualified Person

QP must have detailed knowledge of all steps for which responsibility is taken:

- Product type
- Production processes
- Technical advances

The hard facts for a QP always in connection with GMP

- A QP has to make the market release decision based on data.
- A QP has to rely on data, figures and documents not prepared by a QP.

If data are not reliable ➡

There is not only a risk of financial loss, but primarily a **patient health risk**!

Breach of Data Integrity (BDI)

BDI during manufacturing & testing

Non-compliance with Good Practices in day-to-day operations as required by GMP

BDI during inspections

- Ambiguous, unclear, multiple contradictory answers – an attempt to misguide
- Backdating of documents/creation of documents during inspection
- Delay, limiting and refusal of inspection process

BDI – post-inspection

- Not meeting the timeline provided for CAPA
- Not having supported evidence for CAPA provided

Reference: B. O'Brian, Validant

The Data Integrity -More than Bytes and Signatures

- Efforts to ensure the quality and safety of drugs increase, so does the amount of data generated by those efforts.
  - ➡ As a result guidance and regulatory enforcement strategies are being re-evaluated with a focus on data integrity.
  - ➡ With increasing awareness among inspectorates of problems inherent to data collection and storage, there comes increased awareness of gaps between industry practice and existing technology.

Reference: http://www.gxp-pharmasolutions.com/data-integrity/

Take-Aways

- A QP helps your company maintain a good relationship with the competent authorities
- A QP ensures that all data and information are reliable
- By having a QP in board, you are investing in the future of your business by minimizing patient risk

Contact:

Mag. Gabriela Schallmeiner:
gabriela.schallmeiner@inspection-ready.com

Austrian Qualified Person Association (aqpa):
info@austria-qp.at