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BATCH DISPOSITION

SKILL, QUALIFICATION AND RESPONSIBILITIES

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Speaker:
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SKILL

WHO : Authorized Person

- Responsible for final batch certification, together with the marketing authorization holder,
- Ensure that the quality review is performed in a timely manner and is accurate.
- Part of key personnel
- Education : chemistry (analytical or organic) or biochemistry; chemical engineering; microbiology; pharmaceutical sciences and technology; pharmacology and toxicology; physiology; other related sciences.

SKILL

EU : Qualified Person

- Legal basis for the qualified person is detailed in the European Directive 2001/83/EC issued on Nov. 6, 2001, relating to medicinal products
- Four years theoretical and practical university study in pharmacy.
- A university study in medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, or biology may also qualify the applicant. In this case, however, all missing basic subjects from the curriculum of a full pharmaceutical study must be completed by additional studies or training courses.

SKILL AND QUALIFICATION

EU : Qualified Person

- Provide evidence about successful university studies in experimental physics; general, inorganic, organic and pharmaceutical chemistry; analytical chemistry, including analysis of medicinal products; general and applied (medical) biochemistry; physiology; microbiology; pharmacology; pharmaceutical technology; toxicology; and pharmacognosy (the study of medicines derived from natural sources).
- Practical experience at least two years at one or more companies authorized to manufacture medicinal products in the EU.

SKILL AND QUALIFICATION

EU : Qualified Person

- The practical experience should cover the topics of qualitative analysis of medicinal products, quantitative analysis of active substances, and testing and checking the quality of medicinal products.
- The duration of practical experience may be reduced to one year in case of a five-year university program or to a half year in case of a six-year university course
- Must be registered (or approved, depending on the member state's legislation) by the competent authority of the EU member state where the manufacturing license of the pharmaceutical company was issued and the QP is acting.

SKILL AND QUALIFICATION

BPOM : Responsible Pharmacist

- Proper trained with sufficient practical experiences
- Managerial skill

RESPONSIBILITIES
EU

Certify prior to :

- the release for sale, placing on the market, or export in a register or equivalent document provided for that purpose, that each batch of the medicinal product has been manufactured and checked in compliance with the laws of that member state and in accordance with the requirements of the marketing authorization
- before release for use in clinical trials or export that each batch of investigational medicinal product has been manufactured and checked in accordance with cGMPs and its product specification file.

RESPONSIBILITIES
EU

- (product from 3rd country) :
  - each production batch has undergone in a member state a full qualitative analysis, a quantitative analysis of at least all the active constituents, and all the other tests or checks necessary to assure its quality in accordance with the requirements of the marketing authorization.
  - For investigational medicinal products coming from third countries, the QP must certify that each batch has been manufactured and checked in accordance with standards of cGMP at least equivalent to those of the European Union, in accordance with the product specification file.
- Ensure that the said register or equivalent document is kept up to date as operations are carried out
- Provides the competent national authorities a tool to immediately come back to the responsible QP in case of any issue with the batch that was certified and released

RESPONSIBILITIES
WHO

- Ensuring that each batch of finished product has been manufactured, tested and approved for release in compliance with the laws and regulations in force in that country
- Responsible for compliance with technical or regulatory requirements related to the quality of finished products and the approval of the release of the finished product for sale or supply
- Certify each production batch has been produced and controlled in accordance with the requirements of the marketing authorization and any other regulations relevant to the production, control and release of pharmaceutical products

RESPONSIBILITIES
CPOB

- To initiate and participate in validation programs
- To ensure compliance with technical or regulatory requirements related to the quality of finished products ;
- To evaluate/review batch records; to approve or reject, as he/she sees fit, finished products for sale;

BATCH RECORD REVIEWER/BATCH DISPOSITIONER
Required Skill

- Relevant education background and or experiences
- Sufficient understanding of :
  - Manufacturing process end to end
  - Pharmaceutical Quality System
  - Facilities and Utilities (HVAC/Water System)
  - Supply and Distribution
  - Validation and Qualification
  - Material Management
- Risk Management Skill

BATCH RECORD REVIEWER/BATCH DISPOSITIONER
Required Skill

- Strong personality
  - Passionate to quality as well continuous improvement
  - Speak up attitude and able to deal with conflict
  - High integrity
  - Smart risk taker, by balance between quality and business risk but putting patient safety factor as the utmost important aspect
  - Decisive
  - Open mind
  - Walk the talk

BATCH RECORD REVIEWER/BATCH DISPOSITIONER
Exercise 1

- Which situation that batch is highly likely can be salvaged :

  A. Tablet that contaminated with metal

  B. Tablet that contaminated with glass

BATCH RECORD REVIEWER/BATCH DISPOSITIONER
Exercise 2

- Which situation that batch is highly likely can be salvaged :

  A. Tablet that found less API due wrong dispensing

  B. Final blend granulation that inhomogen

BATCH RECORD REVIEWER/BATCH DISPOSITIONER
Exercise 3

- Content Uniformity tablet X was analyzed by taking 10 tablet as follows : Beginning 3 tablets, Middle 4 Tablets, End 3 tablets. Tablets from end part were found out of specification (to high and RSD out of range). After further investigation, the end-samples were represent the end of process (from last granules in the tablet hopper). What would you do with the batch?

  A. Reject

  B. Segregate the batch and partially reject

BATCH RECORD REVIEWER/BATCH DISPOSITIONER
Exercise 4

- Disintegration of the tablet was found out of specification, which was too fast compare to specification. However the dissolution result meet specification as well as the friability tablet Based on trend it shows the DT always at lower limit but within specification. What would you do with this batch

  A. Immediate Reject the batch

  B. Consult with RA

SUMMARY

- Process, PQS and GMP regulation understanding are the key aspect → to avoid clueless/baseless decision
- Most of the people we deal with grey situation
- Strong smart risk management will help on making proper decision
- Always put patient safety aspect and registered specification as consideration aspect on making batch disposition

SUMMARY

Note :

What ever decision that made please ensure :

- It is properly written and justification and rational behind, based on facts
- Authorized by managerial level, transparent without hiding, make up or manipulate data (Data Integrity)


GRACIAS
THANK
YOU
ARIGATO
SHUKURIA
BOLZÍN
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TIME FOR QUESTIONS
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