What's New in Update No. 3/2019?

Dear Reader,

this update is all about **packaging material and drug counterfeiting**.

As you are well aware, the outer packaging does not only protect the drug product against damage, it also provides the most important information on the drug product itself. In Europe, the outer packaging has got an additional task since February 2019: supporting the fight against counterfeit medicines by means of new safety features. What are the authorities' expectations on serialisation? What questions arose during planning and implementation of the new drug verification system? This is comprehensively addressed in a **Q&A published by the European Commission**. Focusing on the practical implementation, this document will certainly help you to clarify arising questions. The chapter on **Serialisation of folding cartons in the pharmaceutical Industry** provides a supplementary overview.

Packaging material suppliers also play an important role in this setting. How can you establish a reliable and trustful cooperation? A case study shows you how an improved dialogue can point the way to cost savings and time reduction for both sides.

Print data play an important role for drug safety as well. Get familiar with the most important GMP aspects when handling print data and check out what to keep in mind when selecting external repro houses.

When it comes to the **design of packaging materials,** GMP aspects already have to be considered at a very early stage. Our experts strongly recommend creating a technical guideline for the development of your Design Manual. This will definitely support to establish solid quality assurance elements.

The new content at a glance:

GMP in Practice	
Chapter 1	1.K.5 Serialisation of Folding Cartons in the Pharmaceutical Industry
Chapter 13	13.A.10 Pharmaceutical manufacturers and packaging suppliers: Ways to an improved dialogue 13.A.11 GMP aspects when handling print data 13.A.12 GMP aspects in the design of packaging materials

GMP Regulations		
Chapter C	C.8.2.1	Safety features for medicinal products for human use Questions and answers – Version 14
Chapter E	E.3.D	ICH Q3D (R1): Guideline for Elemental Impurities

GMP in Practice

Chapter 1 Quality Management Systems

1.K.5 Serialisation of Folding Cartons in the Pharmaceutical Industry

Medicinal products must be safe – one key requirement in this regard is to ensure that patients are protected from counterfeit medicinal products in the legal supply chain. Particular importance is placed on the serialisation of the packaging: The clear labelling of each individual sales package is one possible approach to prevent counterfeit medicines from entering the legal supply chain. To this end, EFPIA has developed an initiative providing for a 2D matrix code. However, the uniform introduction of this code in Europe or even worldwide is opposed by the fact that many countries have already developed their own concepts. The revised chapter provides an overview on regulatory expectations, the EFPIA initiative and serialisation schemes already implemented. (Roland Kleissendorf)

Chapter 13: Packaging

13.A.10 Pharmaceutical manufacturers and packaging suppliers: Ways to an improved dialogue

The requirements placed on pharmaceutical manufacturers and suppliers of primary and secondary packaging materials have changed significantly in recent years. A stronger integration of the packaging supplier into the processes of the pharmaceutical manufacturer is one possibility to meet the various requirements in a meaningful way. The division of responsibilities can result in time savings and cost reductions for both the pharmaceutical manufacturer and the packaging supplier.

The main prerequisite for this is open and respectful interaction between the pharmaceutical manufacturer and the packaging supplier. This also includes the will to create a situation in partnership cooperation from which both parties can benefit. The author presents a case study on the reduction of incoming goods inspections for pharmaceutical packaging materials, and the optimization of artwork and change management for pharmaceutical manufacturers and packaging suppliers (Ilka Henkel).

13.A.11 GMP aspects when handling print data

Print data play an important role in drug safety. This is reflected in the fact that the majority of all product recalls are attributable to errors in printed packaging materials. When you consider the logistical and financial costs associated with a product recall, it quickly becomes clear that handling print data requires clear definitions and defined processes. The generation and control of print data requires technical knowledge and an understanding of GMP. If the preparation is outsourced to an external repro house, these must be selected and audited according to defined criteria. (André Deister, Ilka Henkel)

13.A.12 GMP aspects in the design of packaging materials

The design of packaging also has an influence on drug safety that should not be underestimated. Since the design development of packaging materials tends to take place in an environment far removed from GMP, it is important to pay early attention to quality assurance elements for both the design and the technical implementation. It is recommended to create a technical guideline for the development of the Design Manual. (André Deister, Ilka Henkel)

GMP Regulations

Chapter C EU Directives and Guidelines

C.8.2.1 Safety features for medicinal products for human use Question and answers – Version 14

The Q&A document on safety features should be seen as a supplement to the Anti-Counterfeiting Directive 2011/62/EU and the Delegated Regulation (EU) 2016/161, which entered into force on 9 February 2019. The comprehensive document contains a total of 110 questions and answers, which are assigned to 12 different topics. It sets out frequently asked questions and answers regarding the implementation of the rules on the safety features for medicinal products for human use. The focus lies on providing information on the technical aspects and should help to facilitate their implementation.

Chapter E ICH-Guidelines

E.3.D ICH Q3D (R1): Guideline for Elemental Impurities

In March 2019, the ICH published the final revision of the Guideline for Elemental Impurities Q3D (R1). The reason for this revision is an adjustment of the PDE value for cadmium by inhalation.

Cadmium is now listed with a new inhalation PDE value of 3.4 µg/day. The original value published in 2014 was 1.7 µg/day. This did not agree with the oral and parenteral PDE calculations, as a modifying factor was not taken into

account. Following a public consultation in May 2018, the value was revised and is now corrected.

Service

Do you have any questions regarding the content of the chapters or need additional information?

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