What's New in Update No. 9/2017?

Dear Reader of the GMP Compliance Adviser,

foreign particles in parenteral drugs, lack of trending hygiene monitoring results, and striking failures in aseptic working techniques are only some of the observations in a recent 483 form issued by the FDA to a pharmaceutical company in South Korea. Failures regarding sterile product manufacturing and environmental monitoring are among the Top Five of the FDA's observations. This clearly underlines the importance of industrial hygiene.

What about your industrial hygiene? Are you compliant with regulatory requirements and are your processes up-to-date? Get an overview on responsibilities, organizational aspects and potential sources of contamination in the introductory chapter 11.A *Industrial Hygiene*. You need more details on clothing, hygienic behaviour, health surveillance and successful hygiene training? Take a closer look at chapter 11.B *Personnel hygiene*. It provides plenty of practical information together with sample SOPs as a valuable tool for putting theory into practice.

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GMP in Practice		
Chapter 11 Production	11.A	Industrial Hygiene
	11.B	Personnel Hygiene

Read the short summaries below to get a perfect insight into the new contents at a glance:

GMP in Practice

Chapter 11 Production

11.A Industrial Hygiene

Industrial hygiene is the interaction between personnel and production hygiene. Industrial hygiene measures are absolutely necessary if pharmaceutical production is to be carried out in a GMP-compliant manner. The planning (material and personnel flow) and design (technical features) of the production rooms have a significant effect on the nature of the industrial hygiene measures required. Potential sources of contamination include personnel, starting materials, media, equipment, premises and the process itself. The adequacy of the industrial hygiene measures is monitored on a regular basis. The Head of Production is responsible for industrial hygiene in the manufacturing sector, and the Head of QC for the laboratory sector. Monitoring can be coordinated and evaluated by Quality Assurance in collaboration with Quality Control. (Christian Gausepohl, PhD)

11.B Personnel Hygiene

The requirements for work clothes are directly related to the cleanliness class in which the manufacturing process is carried out. The cleanability, particle release, adequacy and wear comfort of clothing must be taken into consideration as part of the selection process. The clothing must be washed (treated) in such a way that the quality of the fabric is not affected. A gowning instruction containing information about the clothing elements, the correct gowning procedure and changing of clothes should be available in each cleanliness zone and should be trained on a regular basis.

Hygienic behaviour is essential in all manufacturing areas. Special rules of behaviour apply to work that is carried out in clean rooms. Compliance with proper hand hygiene is extremely important.

Health surveillance is used to limit the potential risk of infectious diseases being passed on by personnel in ill health. Self-disclosure questionnaires or questionnaires completed in consultation with the occupational health practitioner are an important aspect of health surveillance.

Regular hygiene training sessions of a high quality are a key element in maintaining compliance with the hygiene requirements. An important aspect of training is the qualification of the gowning procedure. (Christian Gausepohl, PhD)

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