Pharmakons GMP-Quiz

Spørgsmål og svar

Spørgsmål 1:
Er alle involverede i produktionen medansvarlige for kvalitet?

Svar 1: JA
Ifølge EudraLex vol 4, part I, kap 1, Principle: The holder of a Manufacturing Authorisation must manufacture medicinal products so as to ensure that they are fit for their intended use, comply with the requirements of the Marketing Authorisation or Clinical Trial Authorisation, as appropriate and do not place patients at risk due to inadequate safety, quality or efficacy. The attainment of this quality objective is the responsibility of senior management and requires the participation and commitment by staff in many different departments and at all levels within the company, by the company's suppliers and by its distributors.

Spørgsmål 2:
Forventes der altid 100% kontrol af produktet, når der produceres under GMP?

Svar 2: NEJ
Det handler om at have en kontrolstrategi, se fx Principle i Annex 15 – Kvalificering og validering: It is a GMP requirement that manufacturers control the critical aspects of their particular operations through qualification and validation over the life cycle of the product and process. Any planned changes to the facilities, equipment, utilities and processes, which may affect the quality of the product, should be formally documented and the impact on the validated status or control strategy assessed.

Spørgsmål 3:
Er GMP-tankegangen, at kvalitet skal bygges ind i produktet?

Svar 3: JA
Vi har ikke 100 % kontrol for alt på alle produkter, og derfor er det vigtigt at have en kontrolstrategi, der virker. Det står Annex 15, men du kan også kigge i Kapitel 1, under kap 1.4 (viii): A state of control is established and maintained by developing and using effective monitoring and control systems for process performance and product quality.

Spørgsmål 4:
Skal rengøringspersonale på klassificeret område (rene rum) være trænet i GMP?

Svar 4: JA
Se EudraLex vol 4, Annex 1, 37: All personnel (including those concerned with cleaning and maintenance) employed in such areas should receive regular training in disciplines relevant to the correct manufacture of sterile products.

Spørgsmål 5:
Skal alle nye fremstillingsprocesser og væsentlige ændringer af fremstillingsprocessen valideres, hvis fremstiller vurderer, at kvaliteten er uændret?

Svar 5: JA
Vi kan vurdere omfanget af en validering ud fra en risikobaseret tilgang. Men vi kan ikke undlade validering ved indførsel af en ny proces eller en ændring i en proces. Du kan fx kigge i den danske GMP bek. 1358 af 2012 §23, stk. 3: Enhver ny fremstillingsproces eller væsentlig ændring af fremstillingsprocessen skal valideres. Kritiske trin i enhver fremstillingsproces skal regelmæssigt valideres.

Spørgsmål 6:
Kan råvarer fra en godkendt leverandør anvendes i produktionen straks efter, at de er modtaget i virksomheden?

Svar 6: NEJ
Se fx EudraLex vol 4, kap 6, Principle eller EudraLex vol 4, part I, kap 1, 1.9. kap 6: Quality Control is concerned with sampling, specifications and testing as well as the organisation, documentation and release procedures which ensure that the necessary and relevant tests are carried out, and that materials are not released for use, nor products released for sale or supply, until their quality has been judged satisfactory.

Spørgsmål 7:
Skal alle medarbejdere trænes i GMP hver 6. måned?

Svar 7: NEJ
Det er en god idé at følge med, om der er sket opdateringer, som er relevante og finde ud af, hvem der skal trænes. Typisk har medarbejderne selv sat en frekvens for GMP-træning og genopfriskning. Se fx EudraLex vol 4 part I kap 2,2.11: Besides the basic training on the theory and practice of the quality management system and Good Manufacturing Practice, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its practical effectiveness should be periodically assessed. Training programmes should be available, approved by either the head of Production or the head of Quality Control, as appropriate. Training records should be kept.

Spørgsmål 8:
Skal kontraktgivers kvalitetssystem omfatte kontrol af outsourcede aktiviteter?

Svar 8: JA
Du kan læse meget mere om i Outsourced activities (aktiviteter efter kontrakt) i EudraLex vol 4 part I kap 7, 7.4: The pharmaceutical quality system of the Contract Giver should include the control and review of any outsourced activities. The Contract Giver is ultimately responsible to ensure processes are in place to assure the control of outsourced activities.

Spørgsmål 9:
Kan I undlade at opfylde specifikke dele af GMP-reglerne, hvis jeres risikovurdering viser, det er irrelevant?

Svar 9: NEJ
Man kan ikke risikovurdere sig ud af et myndighedskrav. Her skal vi konsultere et af de vejledende dokumenter i EudraLex vol 4 part III ICH Q9: Appropriate use of quality risk management can facilitate but does not obviate industry's obligation to comply with regulatory requirements and does not replace appropriate communications between industry and regulators.

Spørgsmål 10:
Må eksterne håndværkere færdes frit i rene rum, hvis de har minimum 3 års erfaring?

Svar 10: NEJ
Selvom de har været hos jer før, kan jeres procedure være ændret, og hvor skulle de vide dét fra? EudraLex vol 4 part I kap 2, 2.13: Visitors or untrained personnel should, preferably, not be taken into the production and quality control areas. If this is unavoidable, they should be given information in advance, particularly about personal hygiene and the prescribed protective clothing. They should be closely supervised.



Spørgsmål 11:
Omfatter kvalitetskontrol (QC) alle følgende aktiviteter: Procedurer og dokumentation for prøveudtagning, inspektion og test af råvarer, pakkematerialer, mellemprodukter og færdigvarer samt frigivelse?

Svar 11: JA
Selvom frigivelse i din virksomhed finder sted i QA, er frigivelse beskrevet som en aktivitet under kvalitetskontrol i EudraLex vol 4 part I kap 6, Principle. Quality Control is concerned with sampling, specifications and testing as well as the organisation, documentation and release procedures which ensure that the necessary and relevant tests are carried out, and that materials are not released for use, nor products released for sale or supply, until their quality has been judged satisfactory. Quality Control is not confined to laboratory operations, but must be involved in all decisions which may concern the quality of the product. The independence of Quality Control from Production is considered fundamental to the satisfactory operation of Quality Control.

Spørgsmål 12:
Er der krav om et passende antal af medarbejdere og deres kvalifikationer?

Svar 12: JA
Det står fx i EudraLex vol 4 part I kap 2, 2.1. The manufacturer should have an adequate number of personnel with the necessary qualifications and practical experience. Senior management should determine and provide adequate and appropriate resources (human, financial, materials, facilities and equipment) to implement and maintain the quality management system and continually improve its effectiveness. The responsibilities placed on any one individual should not be so extensive as to present any risk to quality.

Spørgsmål 13:
Må lægemiddelfremstiller ændre i lægemiddelformerne nævnt i fremstillertilladelsen (§39 tilladelsen), hvis der er lavet en risikovurdering?

Svar 13: NEJ
Det står ret tydeligt i GMP bek. 1358 af 2012 § 8: Indehaveren af en tilladelse til at fremstille eller indføre lægemidler eller mellemprodukter må ikke uden Sundhedsstyrelsens tilladelse ændre de forhold, der lå til grund for tilladelsen, jf. § 4, stk. 1. (da GMP-bekendtgørelsen blev opdateret i 2012, hed Lægemiddelstyrelsen Sundhedsstyrelsen, så vi har ikke skrevet forkert ☺)

Spørgsmål 14:
Skal du redegøre for, at du ikke har overset en procedure-, proces- eller system-relateret fejl, hvis du mener, at årsagen til en reklamation er en menneskelig fejl?

Svar 14: JA
Det står i EudraLex vol 4 part I kap 8, 8.17: Where human error is suspected or identified as the cause of a quality defect, this should be formally justified and care should be exercised so as to ensure that process, procedural or system-based errors or problems are not overlooked, if present.

Spørgsmål 15:
Har selvinspektion også til formål at finde forbedringer?

Svar 15: JA
Se EudraLex vol 4 part I kap 9, Principle: Self inspections should be conducted in order to monitor the implementation and compliance with Good Manufacturing Practice principles and to propose necessary corrective measures.