Kepler Universitätsklinikum

PP-008

Quality Risk Management: Microbiologic Process Validation for Semisolid Formulations using the Failure Mode Effect Analysis

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Background and Purpose

As a hospital pharmacy with a preparation unit, we offer a wide variety of products for individual patients as well as for stock. In order to ensure quality for the safety of our patients we do combined process validation for defined product groups opposed to single product validation and/or analysis. The aim of the study was to ensure microbiological quality according to the European Pharmacopeia [1] for all our semisolid formulations and to verify defined shelf lives from a microbiological point of view.

Methods and Results

Microbiological quality?

Conformity to EAB 2.6.12?

Prove for given shelf lives from a microbiological point of view?

- 66 different semisolid products
- some for individual, some for stock
- different preparation methods

Microbiological process validation for the product group – which products should be tested?

FMEA – risk analysis (Fig.1)
14 potential risks identified via peer discussion
Risk Number (= frequency of occurrence **x** detectability **x** severity) [2] allocated

Product selection for analysis based on highest Risk Numbers (>20)
9 out of 66 products included
283 samples from 9 products prepared / taken from stock

Samples tested for microbiological quality according EAB
=> *No growth in any sample observed*

Shelf lives validated from a microbiological point of view

Microbiological quality and conformity to EAB proofed

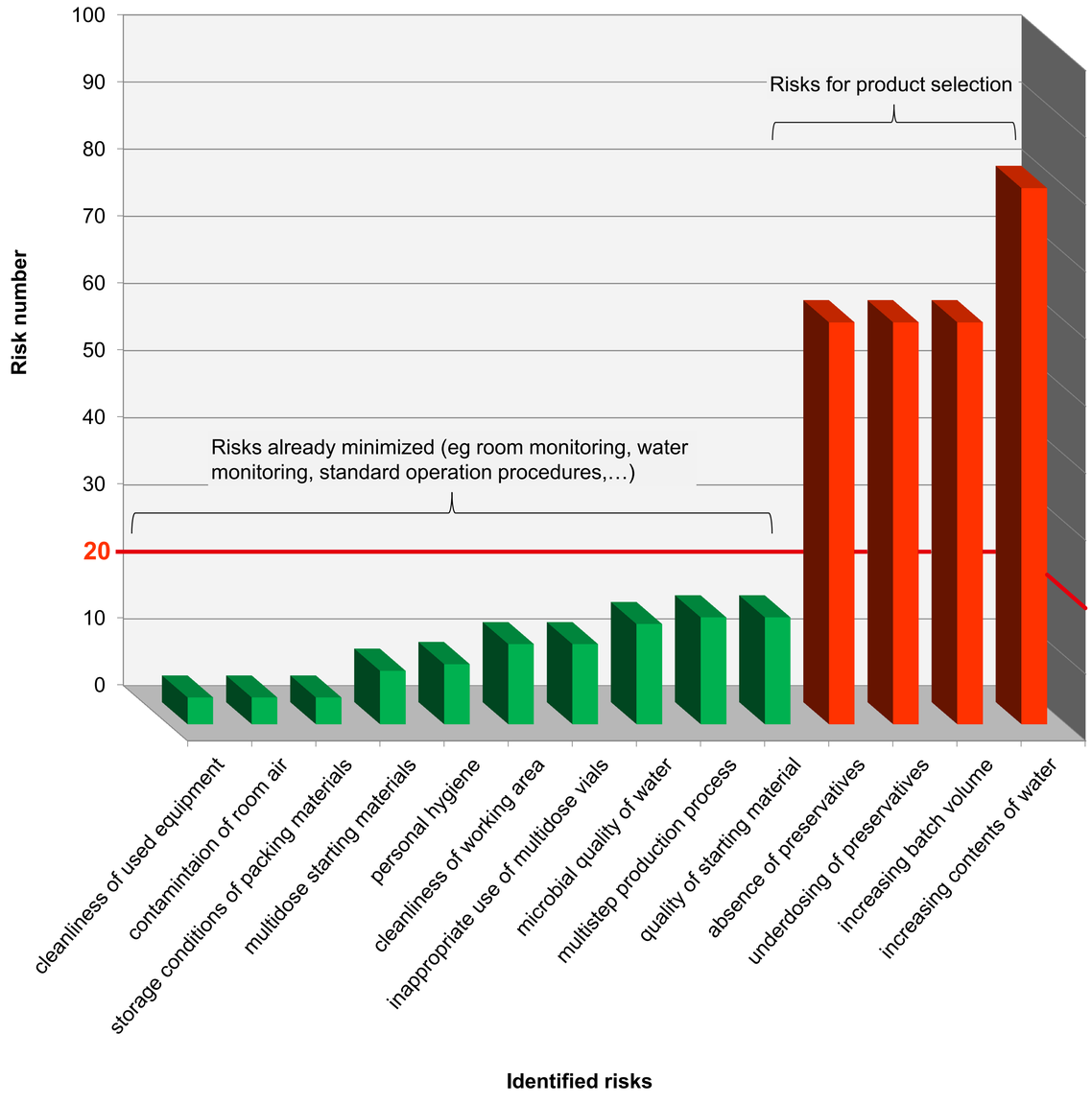

Fig.1.: FMEA – risk analysis

Discussion and Conclusion

Using the FMEA approach to determine and address microbiological risks in semisolid production enabled us to look at a whole product group opposed to every single product. This helps to establish quality with restricted resources of a hospital pharmacy. We were able to show microbiological quality of our semisolid formulations and verify the given shelf lives. Based on this, we are planning to use the same approach for different product groups eg oral solutions.

Referenzen:

[1] Europäisches Arzneibuch. *Halbfeste Zubereitungen zur kutanen Anwendung.* 8. Auflage, S. 1188 (2014). 2014
[2] Bouwman-Boer Y, Møller Andersen L. *Practical Pharmaceutics.* Switzerland : KNMP and Springer International Publishing, 2015.