MANAGEMENT LEVEL

Long standing employees (> 10 years) are of great value.

Common practice to separate QA and QC microbiology departments.

Recognize the impact of highly motivated production personnel.

THE REALITY >>

New trends result in ethnic minorities being the new majority.

They will stay longer.

What worked in the past might not work in the future.

THE CHALLENGE >>

Prevent inappropriate mix-ups.

Control processes to avoid contamination and cross contaminations.

THE SOLUTION >>

Introduce standard workflow processes and continuous training for production personnel.

Objective risk assessment tools are available and easy to use.

Preventive measures are simple to use and ensure a high level of functionality.

RISK ASSESSMENT TOOLS

CAUTION: Microbiologist experts lose oversight during investigations!

CAUTION: QA should have no "police function", but should act as a strong partner!

CAUTION: Considerable staff turnover in global companies!

LEARN FROM THE EXPERIENCE OF A SENIOR QA MICROBIOLOGIST

Schematic overview of the sterile product compliance risk analysis tool can take on value 1 (low), 3 (medium) or 5 (high), depending on the inherent contamination risk and the standard practice used for the respective unit. The tool supports the risk assessment process and enables a high level of transparency and confidence during the risk assessment procedure.

REFS


U.S. Food and Drug Administration Department of Health and Human Services:

www.sciencewriting.at

www.gappquality.com

REFERENCES

1. U.S. Food and Drug Administration: Guidance for Industry and Food Processors - Validation of Hurdle Technologies to Reduce Microbial Pathogens in Foods


CONCLUSION

Improving safety and quality in aseptic processing is a continuous challenge in the pharmaceutical industry. Implementation of an appropriate and consistent risk assessment procedure is a must. The presented approach offers a validated and user-friendly tool to support the entire team involved in the respective departments. It consists of a consistent and continuous procedure to identify risks and evaluate the level of risk associated with aseptic processing. The tool supports the risk assessment process and enables a high level of transparency and confidence during the risk assessment procedure.

INVEST IN

Training of QA lab personnel

A LEADING WORLDWIDE FACILITY WITH SOLID APPROACHES TO RISK ASSESSMENT

STERILITY TESTING FACILITY

SUMMARY

In this article, the author provides a detailed questionnaire based on his knowledge and experience in the field of QA/QC microbiology, sterile production, aseptic processing and regulatory audits. Over the course of nearly a decade, the author developed a detailed questionnaire based on his knowledge and experience in the field of QA/QC microbiology, sterile production, aseptic processing and regulatory audits. Over the course of nearly a decade, the questionnaire evolved into three independent hazard operability analysis (HAZOP) tools that are today ready to hand.

UNITS

UNIT AVERAGE RISK FACTOR

TOTAL RISK FACTOR (TRF)

RISK EMPHASIS FACTOR (REF)

Three different risk assessment tools are available:

Schematic overview of process units and related Risk Emphasis Factors (REFs)

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