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Trustworthy computer systems

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Data integrity is a global problem and currently a major concern in FDA and European Regulatory Agencies. To ensure the integrity of electronic records, it is essential that the system managing these electronic records must be, at the same time, trustworthy. Trustworthy computer systems are the first line of defense to protect the critical electronic records managed by these systems. The driver of the computer systems validation process is to ensure an acceptable degree of evidence (documented, raw data), confidence (dependability and thorough, rigorous achievement of predetermined specifications), intended use, accuracy, consistency and reliability, or that the computer system is a trustworthy system. This presentation describes the concept of trustworthy computer systems in a GMP regulated activity and, the regulatory requirements and key guidelines associated with the trustworthy of computer systems within the scope of the referenced competent authority.

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Improvement of the quality culture through optimal application of quality metrics

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Good Manufacture Practice (cGMP) regulations are based on reaction due to serious incidents and describe the dos and don'ts to achieve products of consistent quality, safety and efficacy. But processes are dynamic and as such potentially may affect the controlled status of medicinal product manufacture. This may lead to undesired and out of compliance situations. During calamities, a properly functioning and metrics based Quality Surveillance System will be able to identify immediate and necessary action for correction, corrective and preventive actions to recover and improve the controlled status. Transformative Quality Cycles (Deming: Plan-Do-Check-Act) clarify the interaction of processes at the operational level for product realization, at the tactical level for the established organization (including the improvement thereof) and all based on strategic goals and objectives. The Critical Quality Attributes within processes are interlinked with Lagging Performance Metrics for process controls. Quality Risk Analyses reveal opportunities for improvement with impact into the Leading Metrics of the established systems creating objectives for Management Review. As such a continuous and lean process approach is obtained leading to a quality culture wherein cost reduction through awareness and commitment is the direct spin-off. The surveillance system results in a network of Lagging and Leading Performance Metrics. Applying Quality Risk Management, the evaluation of performance results provides objective input to the Management Review. The usability of the metrics model is demonstrated by analysing recent FDA Warning Letters and identifying required actions.

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