Learn About the Latest Updates to the GMP Guidelines

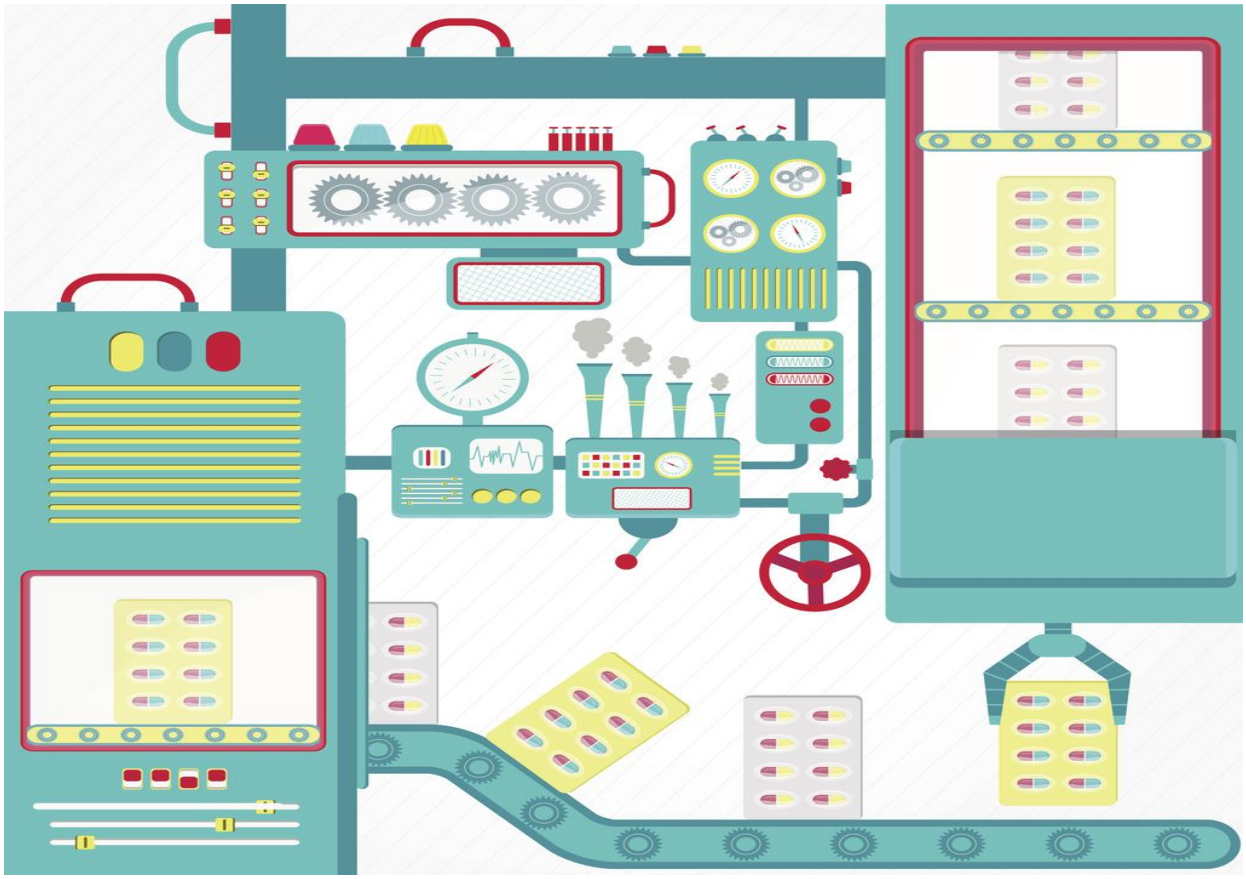
The manufacturing environment and regulatory setting in Pharma are changing. There is a continuous adoption of new approaches when it comes to **Good Manufacturing Practice (GMP)** by researchers and other practitioners. Progressive technologies are coming into play as well, in attempt to streamline the landscape of drug manufacturing, the Clinical industry, the Research sector and healthcare in general. Consequently, clinging on to outdated requirements which do not apply to the current state of all of those fields becomes a practice which holds practitioners back. To succeed in this undertaking quite often it means to implement and be compliant with relevant and updated rules. In this sense, **the EU Guidelines for GMP for Medicinal Products for Human and Veterinary Use has been updated.** The European Commission has revised several key annexes to the GMP guidelines, including **Annex 15: Qualification and Validation, Annex 16: Certification by Qualified Person and Batch Release, and Annex 17: Real Time Release Testing.**

Astra Nova recently released an updated version of the GMP certification course which contains all the relevant changes applied to the guidelines.

In brief, our course takes into account the revised Annex 15. The information is much more comprehensive and is complemented by couple of completely new chapters. One of the most important

aspects in the improved document is risk assessment. A special emphasis is placed on having adequate qualification and validation procedures. And because having a Validation Master Plan (VMP) is very critical, the content regarding this matter has been extended significantly. All qualification stages for facilities, utilities, equipment and systems have been clarified and explained as well. Couple of new chapters have been added. They include: Requalification, Transport Verification, Packaging Validation, Qualification of Utilities and Validation of Analytical Methods.

Next, since changes to Annex 16 have been made as well, we made sure to enrich the context of our GMP course with the latest specifics and requirements, considering the **introduction of innovative quality control techniques and strategies. We have covered the process of certification, highlighted the proper process of a** batch release and explained how the qualified personnel should handle unexpected deviations.



Regarding the revised Annex 17, our course provides with well-structured information regarding the appropriate incorporation of Real Time Release Testing (RTRT) approaches. We underlined important criteria which should be established, while designing an RTRT strategy and an RTRT related master plan. There are key notes regarding the sterilization process as well as the application of parametric release to different products as well.

Why is GMP important?

Maintaining Good Manufacturing Practices is crucial for the safety, integrity and quality of pharmaceuticals. **A GMP system ensures that medicinal products are adequately controlled and manufactured in order to be safe for human consumption.** Therefore, having the skills of a professional and gaining the necessary knowledge on GMP becomes a priority to practitioners. That's why we designed our GMP certification course in a comprehensive, well-structured and engaging way. **It is suitable for researchers, validation personnel, operation and manufacturing staff, Quality Assurance and Quality Control professionals, industry newcomers and others.**

More information about available corporate discounts and full content of the training can be found here.

References: http://www.gmp-compliance.org/eca_index.html [last accessed: 05/01/2017]

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