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Continuous manufacturing

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Continuous manufacturing (CM) of pharmaceutical products is among other trends like additive manufacturing one of the dominating topics in advanced manufacturing in the 21st century. The importance and relevance of CM is indicated by the step 2 draft of ICH Q13 on "Continuous manufacturing of drug substances and drug products"1, which was published in July 2021. Several types of CM are covered by the draft guideline: drug substances, drug products, therapeutic protein drug substances and integrated drug substance and drug product CM.

The presentation focuses on drug product CM, especially solid dosage forms. First products are on the markets in US, Europe and Japan. The number of CM products is limited so far, but the number will raise soon. Some companies have a clear strategy that a significant portion of products in their portfolio will either be converted to CM or be produced by CM right from the beginning. Some of the existing CM products are made by direct compression, which requires a short process trail with relatively low complexity. Integrating other process steps like roll compaction/ dry granulation or wet granulation and drying is more demanding.

CM has a number of advantages, which can generally be related to an increase in quality or a reduction of costs. However, in order to realize these advantages a number of problems and hurdles have to be eliminated. CM requires a new way of thinking, a new mindset, in all participating parts of a company like management, development, production, quality control and quality assurance2. Furthermore, not only the pharmaceutical companies have to make progress, but also machine suppliers, who have to integrate their unit operations into a CM-line, implement suitable PAT methods, develop hierarchical architectures for (advanced) process control etc. Excipient suppliers can contribute by offering tailor made excipient grades for CM. Finally, the authorities also have to adapt the concepts of CM and to understand the differences to batch manufacturing. All in all, CM requires less, but highly educated staff. Academia and scientific organizations can train experts that are able to handle the important topics of CM. A lot of research is done at Universities and there are still a lot of exciting scientific questions to be answered.

Collaboration between the stakeholders are crucial to develop the field. Some examples of consortia in this field are shown.

References

1. ICH. Q13 Continuous manufacturing of drug substances and drug products. https://database.ich.org/sites/default/files/ICH_Q13_Step2_DraftGuideline_%202021_0727.pdf

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