HOW TO IMPLEMENT IV ROBOTICS IN GMP ASEPTIC PRODUCTION

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Background and purpose

Denmark is one of the European countries that requires the Good Manufacturing Practices (GMP) certification to hospital pharmacies in order to compound medication.
In 2012 the Capital Region Pharmacy, the largest hospital pharmacy in Denmark, decided to invest in IV robotics to guarantee EU-GMP and GAMP compliance through the highest standards of safety, quality and efficacy in the compounding process.
The go-live of this technology was preceded by a tough qualification aimed at assessing the new compounding process was GMP compliant. The GMP qualification consists of several validation procedures in sequence: Design Qualification, Factory acceptance test, Operational qualification, Installation qualification and Performance qualification.
This poster illustrates a case study on how the technology can help hospital pharmacy to be GMP compliant.

Material and metod

A dedicated multidisciplinary team studied thoroughly the reference documentation: EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use. The analysis led to the definition of 89 User Requirements Specification (URS) associated to GMP requirements, on a total of **143 URS** addressed in the tender. The GMP requirements cover several aspects like environmental conditions,equipment design, product safety and efficacy, Documentations, Alarms alerts, User accessibility, training and maintenance, data storage and record. During the tender, the competing systems were challenged on each URS to verify their compliance.

September 2012
Procurement

October 2012
Supplier Audit

January 2013
Design Qualification

January 2013
Factory Acceptance Test

May 2013
Installation; Site Acceptance Test

June-September 2013
Training

June 2013
Design Qualification

July 2013
Operation Qualification

August 2013
Performance Qualification

September 2013
Go Live

November 2013
#1 GMP inspection and certificate

October 2014
#2 GMP inspection and certificate

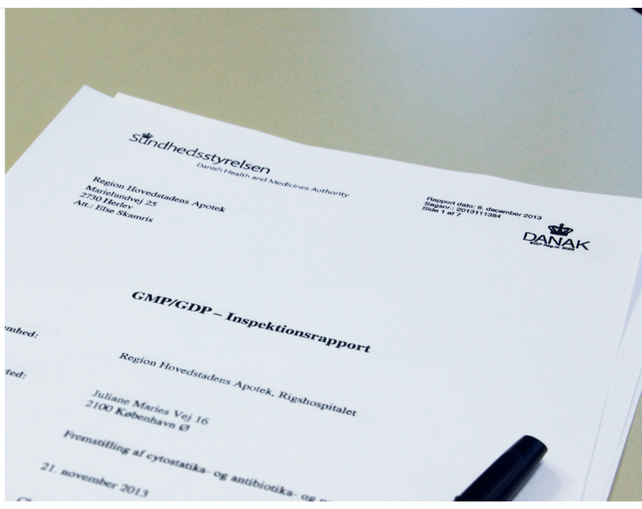
August 2015
#3 GMP inspection and certificate

September 2016
#4 GMP inspection and certificate

Supplier Audit

Site Acceptance Test

Go Live



GMP inspection and certificate

Results

The system that scored best in the tender evaluation was APOTECAchemo.
It fulfilled **74** of the **89 GMP** requirements from the beginningand the manufacturer developed and validated the additional 15 before the qualification process. In November 2013 the Danish Health and Medicines Authority certified that **APOTECAchemo was totally compliant with the GMP regulations** and authorized the go-live. Since November 2013 **3 additional inspections** have been successfully passed, without any deviation. Moreover, they approved the use of this robotic system in a **class C** cleanroom, differently from the manual compounding that now requires a class B cleanroom.

Conclusion

The installation of an IV compounding robot in full compliance with GMP regulations ensures benefits in terms of the highest level of preparation quality, operator safety, continuous monitoring of environmental condition and reduction in human interventions in controls and reports.

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