

# Certificate



EUROPEAN COMPLIANCE,  
ACADEMY

**Mr. Honoriu Pavel Dumitrescu**

has completed a four day ECA GMP Education Course from  
9 - 12 December 2019 in Copenhagen, Denmark covering the following subject

## ***Pharmaceutical Engineering***

### **Contents of the Course:**

An Overview - How Engineering impacts on GMP and the Regulatory Area  
Overview - The important Documents in the Pharmaceutical Industry  
SOP- Requirements and Basic Rules of Writing  
FDA-Compliant Design of Vessels, Piping, Valves and Gaskets  
Hygienic Design Principles and Practical Examples  
Qualification and Validation, Risk Analysis, URS/FDS, DQ, FAT/SAT  
IQ, OQ, PQ - Requalification, Process Optimization, Process Validation, Cleaning Validation  
GMP-compliant Management, calibration in Pharmaceutical Production Processes  
Change Control/Deviations, Audit  
Workshops: Documentation - SOP, GMP-conform Design, Qualification

Heidelberg, 12 December 2019

Signature of Course Leader

In co-operation with

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