

Certificate



EUROPEAN COMPLIANCE
ACADEMY

Mr. Honoriu Pavel Dumitrescu

has completed a four day ECA GMP Education Course from
9 – 12 December 2002 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 2002

Signature of Course Leader

In co-operation with

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