



QPLN WP-3

University of Medicine and Pharmacy Carol Davila Bucharest (P9)

Prof. Constantin Mircioiu

*Quality Assurance in European Pharmacy Training and Education PHAR-QA
QA-PLN WP-3 KO 30/09/2012, Brussels*

Pharmine



Education and Culture DG
Lifelong Learning Programme



PHAR-QA
Quality assurance in
pharmacy education
and training in Europe

Education & Culture DG
Lifelong Learning Programme



Universitatea de Medicină și Farmacie “Carol Davila” București



The Faculty of Pharmacy of the University of Medicine and Pharmacy “Carol Davila”, Bucharest is the **oldest and main education provider** in the pharmaceutical domain in Romania (1200 students).

Education of students is organized as a **five years bachelor-master integrated cycle** and a **3 years Ph.D. cycle**.

Main objective of the faculty in the next years is **tuning of curricula** in order to **offer a better chance** to graduate students in the **European labour market** and the **enlargement of the master cycle**, based on the experience of other pharmacy faculties participating in the project.

Bucharest team (P9-UMFCD)

- Lead WP QPLN
- Assistance with statistical analysis in WP IMPL



Prof. Constantin MIRCIOIU

PROJECT MANAGER

- Involved in all *phases*

Education

- MD in Pharmacy, - MD in Mathematics,
- Professor of Biostatistics.

University positions

- Dean 2004 - 2008,
- Scientific Secretary ("Chancellor ") (2008-2012)

Consultant and expert

- Organizer of several international scientific meetings.
- Member of the Management Committee of COST B 15 Action - "Modeling in Drug Development" 2003 - 2005; COST B 25 Action - "Physiological Modeling in Pharmaco/Toxico Kinetics and Dynamics" 2005 – 2009.
- Co-chair of Joint Master Program in Biostatistics (Faculty of Pharmacy and Faculty of Mathematics)
 - Member of the Scientific Advisory Committee of ECVAM , JRC Ispra, 2006 - 2009.





Prof. Dumitru LUPULEASA **RESEARCHER**

Involved in the *Build* and *Engage* phases

Education.

1972 – graduated as pharmacist.

Training stages: 1990 (Montpellier), 1991 (Los Angeles), 1992 (Paris) : development of pharmaceutical dosage forms

University positions and other positions.

Dean 1996-2004, 2008 –

President of Romanian Association ("College") of Pharmacist

Professor of Pharmaceutical technology and Industrial Pharmacy,

Consultant and expert

Head Pharmacy Directorate of the Ministry of Health 2000 -2003,

Member in Scientific Council of some pharmaceutical companies

Research interests

Pharmaceutical technology, management in community pharmacy, Health Care System Management



Lecturer Flavian Ștefan RĂDULESCU RESEARCHER

Involved in the *Build* and *Engage* phases

2006 -**Inspection and Audit certification Good Clinical Practice**: Training Auditing Consulting, University of Cardiff.

-2006 - Basics on Good Clinical Practice for **Monitors Good Clinical Practice**

-2004 -Specialist for **Quality Management Assurance System, TUV Rheinland-Berlin-**

University positions and other positions - 2009-Present - Lecturer

-**Specializations:** 2011 - basic training microdialysis techniques for drug release evaluation after topical administration, University of Copenhagen Arndt-Universität Greifswald Certificate. Training in Experimental in-vitro Methods for Evaluation of Metabolism, Dept.of Pharmaceutical Biosciences, University of Oslo; 2011- basic training, in vitro drug release techniques, Ernst-Moritz

Experience in industry and clinical studies.

Research interests: Project, approval and implementation of clinical study protocols; audit and **monitoring** of all clinical study phases; establishing **standard operation procedure systems**;

Assistant Prof. Cristina RAIS RESEARCHER

Helping with the *Grip, Build and Engage* phases



2007 International **Research and Innovation Management Summer School**",

PhD in Medical Sciences/Pharmacy

2005- 2008 – Specialization in Pharmaceutical Industry

2000-2005 -License in pharmacy;

Bachelor in economical sciences, Fac. of Management and Marketing in Economic Affairs

Assistant Professor, Dep. of Management, Marketing and Pharmaceutical Legislation

2005-2010 - Pharmacist in community pharmacy

from 2011 – evaluator in National Agency for Medicines and Medical Devices

Research interests

Definition of quantitative criteria for measuring tuning degree between different educational units.

Definition of procedures for quality system of Academia-Research-Industry cooperation.

Identification of ethical aspects and needed rules for pharmaceutical research.



Assistant Prof. Valentina ANUȚA
ADMINISTRATOR
Involved in the *Build* phase

Long experience in elaboration of reports in the frame of research grants of the biopharmaceutical research group of the faculty
Connection with financial organizations for auditing the projects.
Elaboration of GLP audit reports in the bio-analytical laboratory.

2007-2010 -PhD in Medical Sciences/Pharmacy

2006-2008 -Specialist Degree in Pharmaceutical Laboratory

2000-2005 – Pharmacist

University and other positions

Feb 2006-present - **Assistant professor** , Physical Chemistry Department

Oct 2001- Apr 2009 - Bioanalyst at S.C. Biopharmacy and Pharmacol Res S.A,

General objective of "QA-PHAR" QPLN

Inspecting the accomplished work in the project in order to ensure the alignment with the proposal:

- ☐ Overall vision
- ☐ Strategy
- ☐ Principles
- ☐ Values

Quality Assurance in European Pharmacy Training and Education PHAR-QA

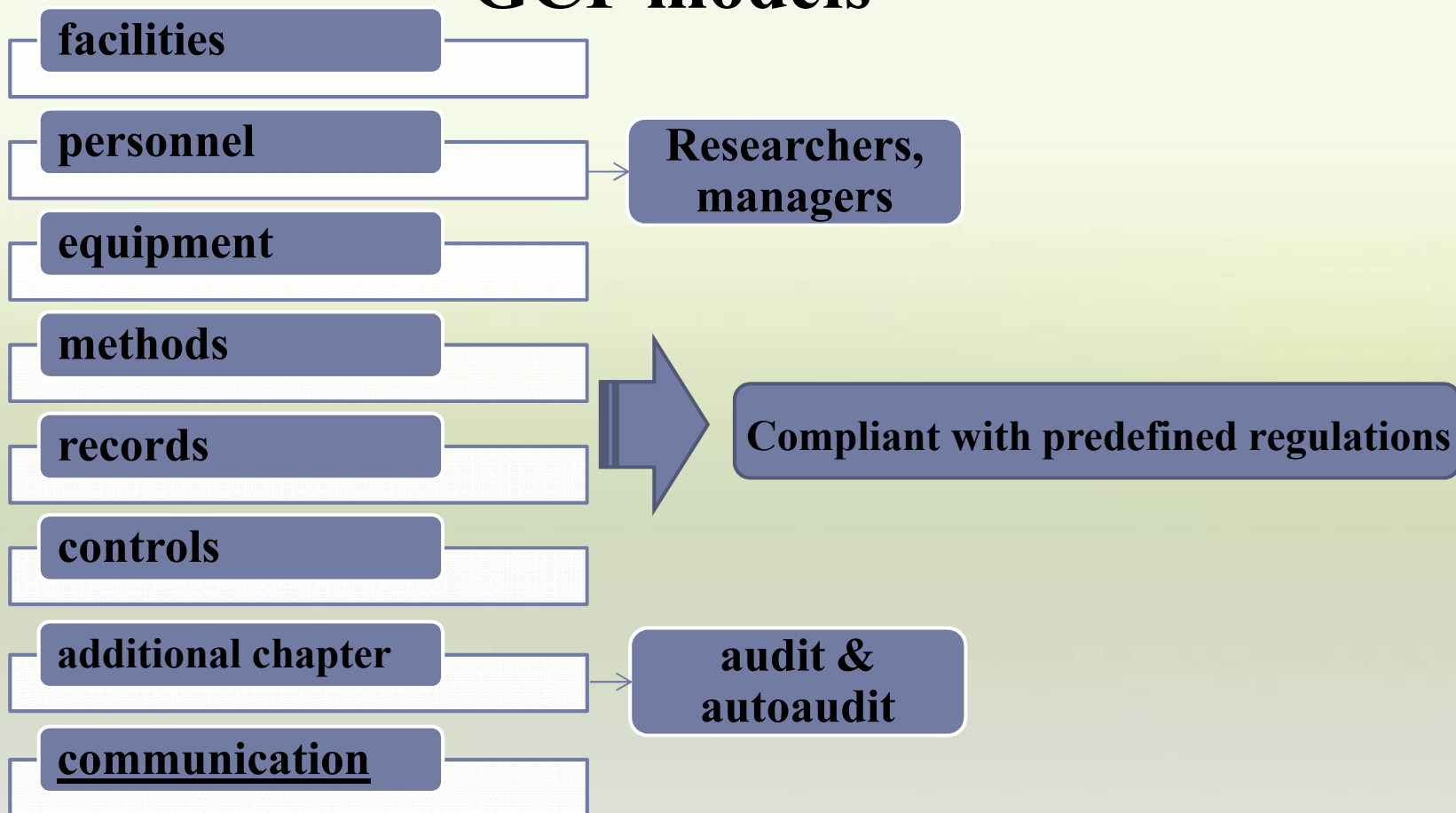
QA-PLN WP-3 KO 30/09/2012, Brussels



HOW IS TO BE PRODUCED

PRINCIPLES AND METHODS

Regulatory approach methods: GLP, GMP, GCP models





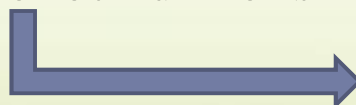
Mathematical and cybernetic approaches

Basic Principle: Feedback adjustments

3.1. Grip



Establishing the foundations



SOP

Preliminary
Report

3.2. Build



Training and education



M18 Report

Questionnaires

3.3. Engage model



Gauging effectiveness

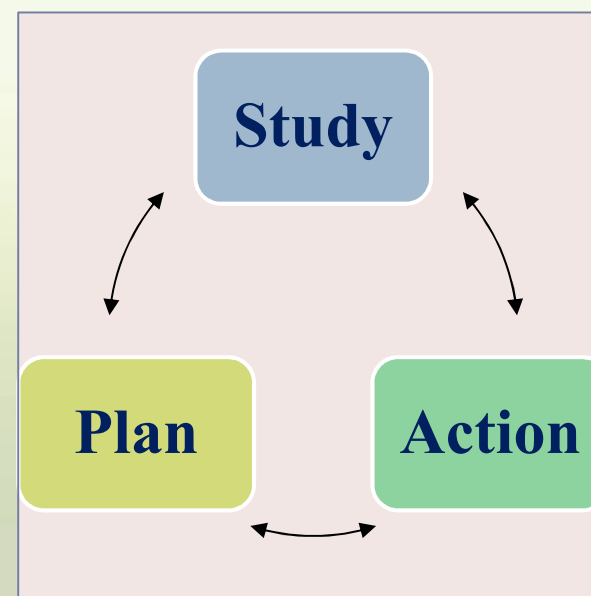
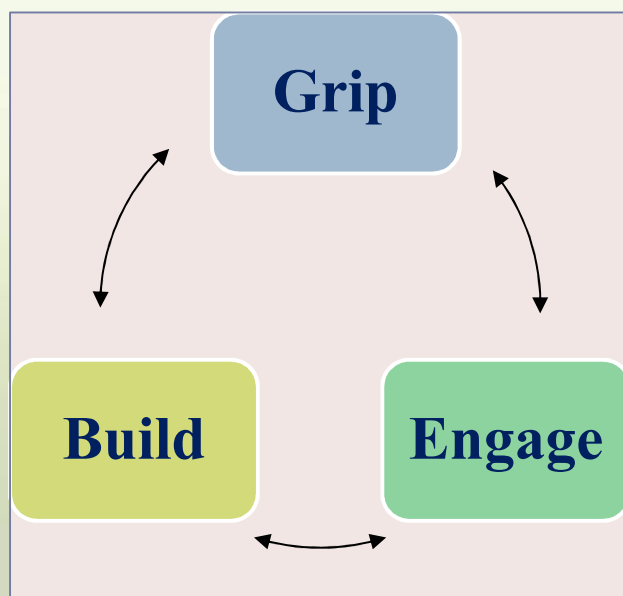


M36 Report

Addressed to
participants and/or
WP1 members
-meeting reports

Mathematical and cybernetic approaches

Basic Principle: Feedback adjustments



Evaluation / decision / action _Branch-out_

Evaluation:

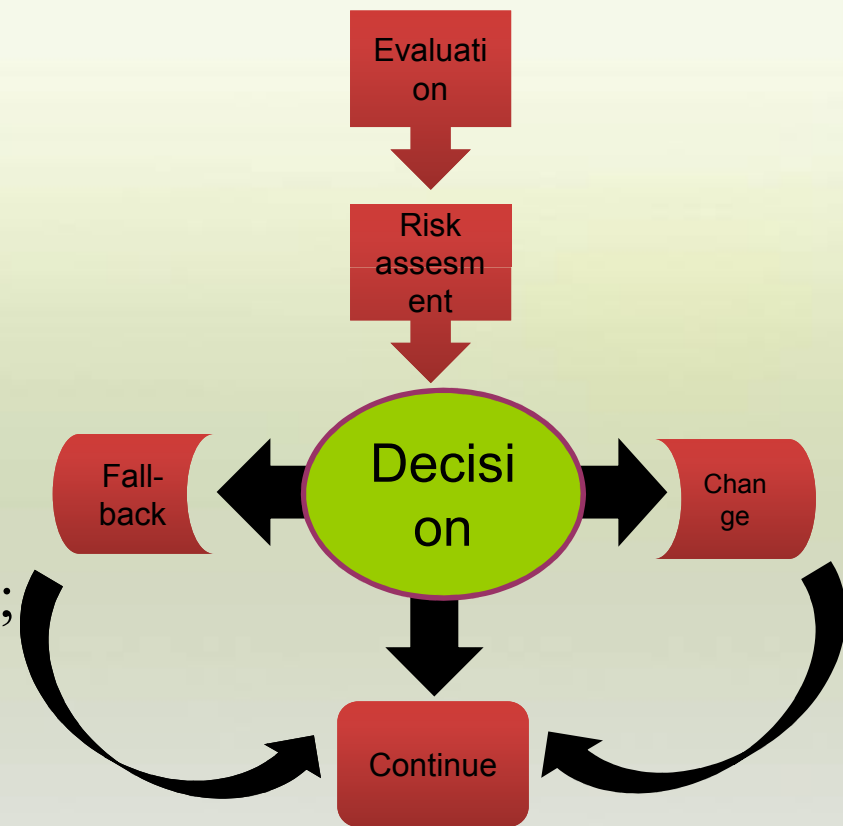
- ▶ effectiveness of the work;
- ▶ root causes of ineffectiveness.

Risk assessment:

- ▶ high/medium/low risk involved.

Turns in Action:

- ▶ **continue** programme element, redistribute task, funding, resources;
- ▶ **change** programme element;
- ▶ **adapt** fall-back position;
- ▶ further evaluation/**no action**.



Tools

- ▶ **Questionnaires**
- ▶ **Statistical analysis of questionnaires:**
 - **Likert summative score scales: mean, variation, correlation, Cronbach reliability & score, LOO**
 - **Global and in groups and subgroups of items/responders.**
- ▶ **Iterative Delphi methods for obtaining consensus.**

Activities of WP QPLN:

- ▶ monitoring timely audit reporting;
- ▶ to assure effective communication between advisory board and QPLN;
- ▶ to check compliance documentation (incl. deviations and investigations) are reviewed in timely manner;
- ▶ monitoring of corrective actions and follow-up, if applicable;
- ▶ *evaluation of the extent to which the QPLN can be applied in future developments of QA in PET in WP EXP.*

Deliverables – 3.1

1. **Collaboration with WP MNTG and WP IMP**
2. **Defining the principles for QA and monitoring**
3. **Discussion, editing, revision of SOP and rules of engagement**
4. **Report / feedback to consortium for action initially by P1 and P2, then decision by WP MNGT**

Deliverables – 3.2

Report

- ▶ Interaction with **all partners** $\Rightarrow$ improve awareness of QPLN
- ▶ Ensure:
 - ▶ **existence of good communication**
 - ▶ **efficient dissemination**
- ▶ Information of consortium concerning:
 - ▶ **applicable rules and regulations of QPLN**
 - ▶ **future developments**
- ▶ **Collection of data concerning QA by questionnaires. Statistical analysis and harmonization.**
- ▶ **E-mail exchanges & preparing sessions in WP MNTG meetings**

Deliverables – 3.3

Report

- ▶ Reports and feedback for action, initially by **P1** and **P2**, then to consortium to evaluate efficiency and a basis to the establishment decision by **WP MNGT**.
- ▶ Retirement to predefined fall-back position (reserve alignment) and/or restart the actions
- ▶ Elaboration of audit reports (M18, M36).

FINAL DELIVERABLES

- ▶ **identification and monitoring of 10% of events that generate results;**
- ▶ **refining the previously implemented techniques and tools (PHARMINE WP6 / QPLN).**

Timing and Deadlines

- ▶ **Data collection M1-M16. Data analysis and preparation of report M16 - M18. Presentation of Report M18.**
- ▶ **Data collection M19-M30. Data analysis and preparation of report M30 - M36. Presentation of Report M36.**

