

**LINKING PHARMACY  
EDUCATION, RESEARCH  
AND TRAINING WITH  
EMPLOYMENT**

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*Τμήμα Φαρμακευτικής ΑΠΘ*

GMP guidelines in:

ICH Q8

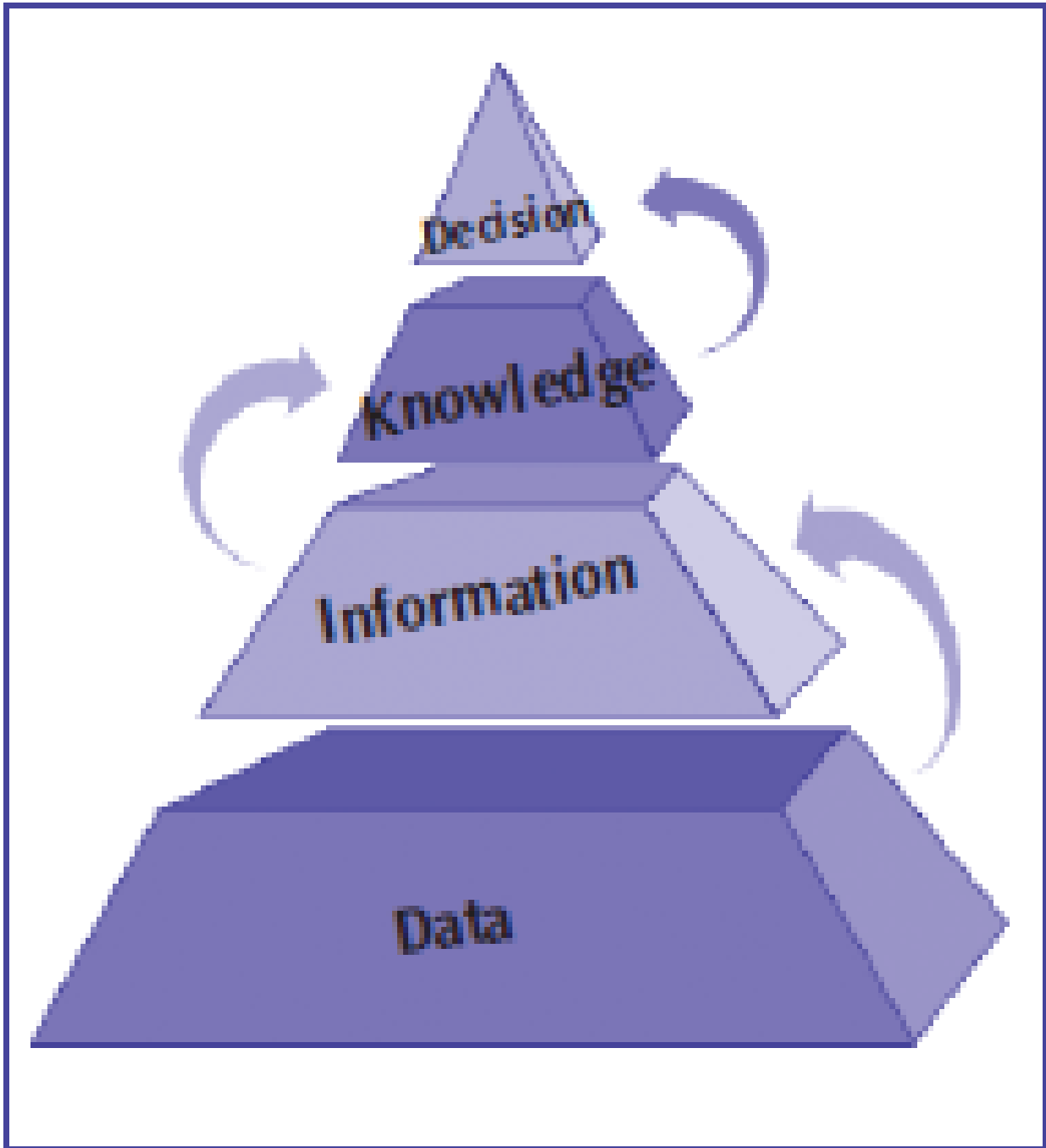
Pharmaceutical Development

*Implications:*

- understanding of how formulation and process factors impact on product performance
- Continuous real time assurance quality



The QPs need to understand the processes before making decisions



GMP guidelines in:

ICH Q9

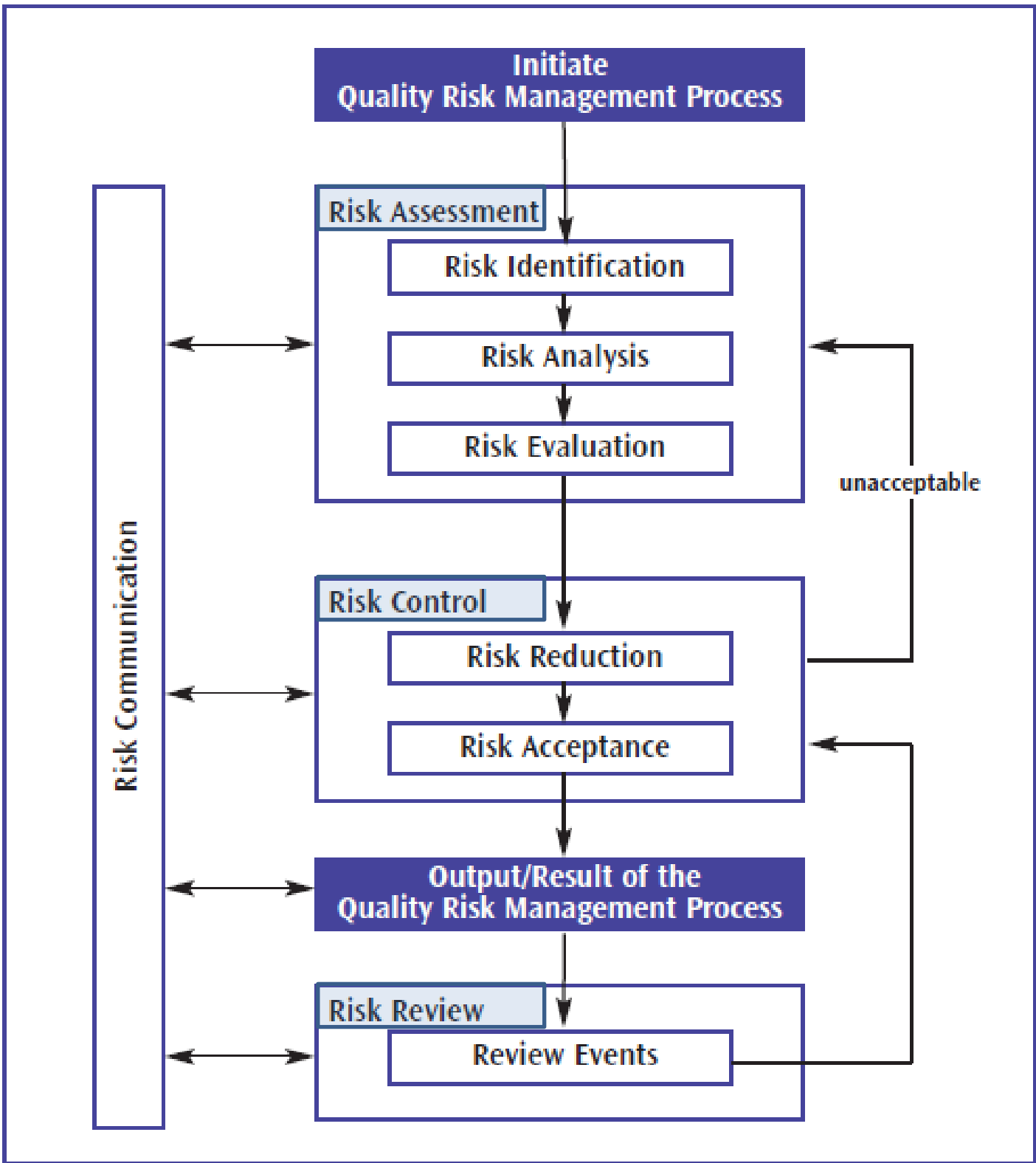
Risk Management

*Implications:*

- So far risk assessments to justify 'bad decisions'
- Now risk management process for proactively working on prioritised risks



Final risk acceptance decision  
or 'Who is going to approve  
the Risk Acceptance docs?'



GMP guidelines in:

ICH Q10

Quality Management System

*Implications:*

- So far QP's role is to implement and maintain the QMS and ensure that Product Quality Review is performed timely
- Now 'senior management' is responsible for the QMS and the QP guard or auditor?



The QPs need to understand the content and implementation of QMS

GMP guidelines in:

ICH Q11

On development and manufacture of Drug Substances (al the way to drug synthesis route; manufacturing process and controls, selection of starting and source materials, process validation/evaluation)

*Implications:*

- Inspection required at the manufacturer's site
- For imported drugs also at the entrance port
- How extensive?

“WHAT” ? described in the guidelines



“HOW” is implemented?



“DECISION MAKING” or  
“WHO” will be responsible for leading,  
managing and making key decisions?



# Implementing the GMP guidelines in ICH Q8, Q9, Q10 & Q11 on the European Qualified Person

QP role essential for the successful implementation of guides, Keeping at the same time smooth operations



**ACTIONS - INITIATIVES**

## LINKING INDUSTRY & ACADEMIA IN TEACHING PHARMACEUTICAL DEVELOPMENT & MANUFACTURE (LIAT-Ph)

- The pharmaceutical industry continues to develop to respond to challenges of an ageing population and more complex products
- Advances in pharmaceutical development including a shift towards QbD, the increasing importance of biopharmaceutical products and the move to stratified medicines, will result in larger company product portfolios



- Industrial pharmacists should be equipped to respond to the challenges of the changing work environment

### **Therefore there is need for:**

- a rapidly increasing knowledge base,
- a need for specialized knowledge, and
- the necessity for partnership and
- **closer collaboration between academia and industry has been recognised on the national, and EU level.**

# **EPSA INDIVIDUAL MOBILITY PROJECT**

**The European Pharmaceutical Students' Association (EPSA)**

**Individual Mobility Project (IMP)**

- **IMP is a long term internship project that gives the opportunity to students and recent graduates from to gain :**
  - **real-time work**
  - **research experience in any field of pharmaceuticals**
- **It is a unique network developed to offer international professional experience for students with:**
  - **strong professional and personal ambitions as well as to those**
  - **who are undecided or confused about their professional future path and wish to explore the opportunities in any kind of pharmacy-related professions.**

# PHARMACY STUDENTS



**What my family thinks I do**



**What I am supposed to do**



**What I think I do**



**What I really do**

# COMPETENCES FOR INDUSTRIAL PHARMACY PRACTICE IN BIOTECHNOLOGY

- There is a lag-time in knowledge transfer between industry and education
- In contrast to industry, educational programs change slowly
- Industry needs to change direction and policy within months to remain competitive
- The educational system should provide courses to produce the right person on time
- The missing link : system whereby universities can obtain feedback from industry on what they should be teaching



- PHAR-IN has developed a Delphi tool for such a feedback process offering a rapid reaction in a quickly evolving field leading to the creation of cutting-edge courses

**Further information in  
the EIPG (European  
Industrial Pharmacists  
Group) Journal at:  
[www.pepharm.gr](http://www.pepharm.gr)**

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THANK  
YOU