The industrial perspective: what are the unmet needs

2018 EAFP Annual Conference
Pharmacy education: towards pharmaceutical sciences

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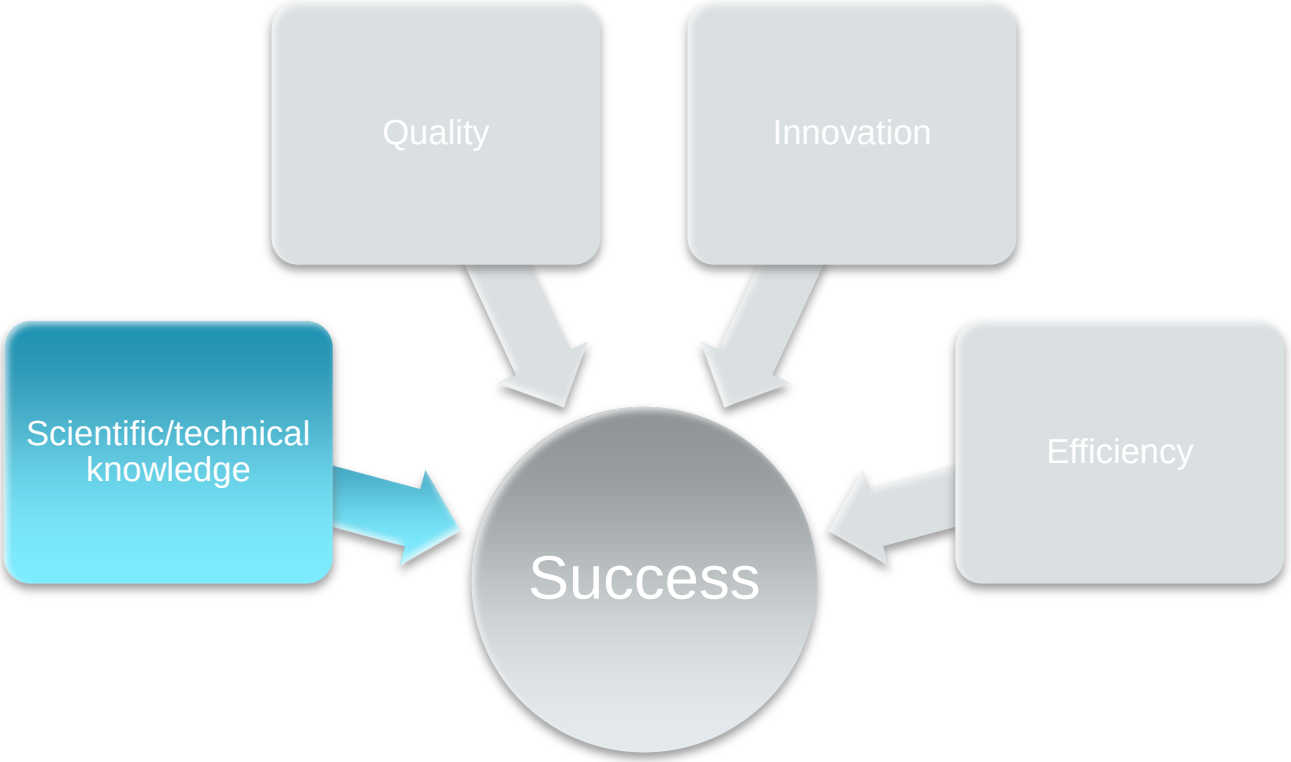
Chiesi
People and ideas for innovation in healthcare

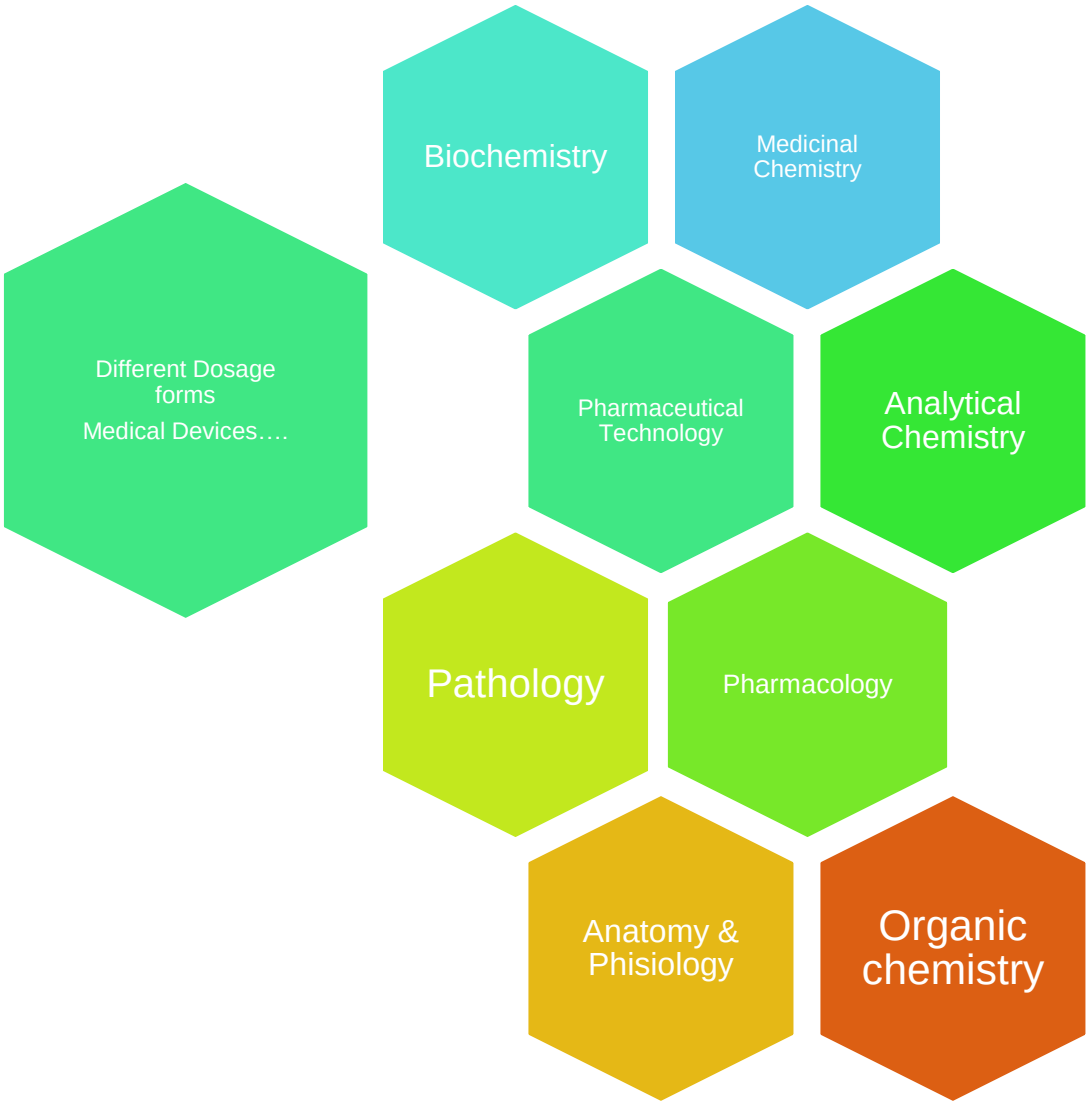
WHICH ARE THE PHARMACEUTICAL COMPANY (MAIN) NEEDS

PROVIDED THESE NEEDS,
WHICH SKILLS SHOULD BE INCLUDED IN THE EDUCATION?

WHICH ARE THE PHARMACEUTICAL COMPANY (MAIN) NEEDS



PHARMACY EDUCATION: obvious (and expected) knowledge



√ Scientific/technical knowledge

SUGGESTIONS:
Give focus to product development steps , including explanation on clinical Phases, toxicological evaluation…

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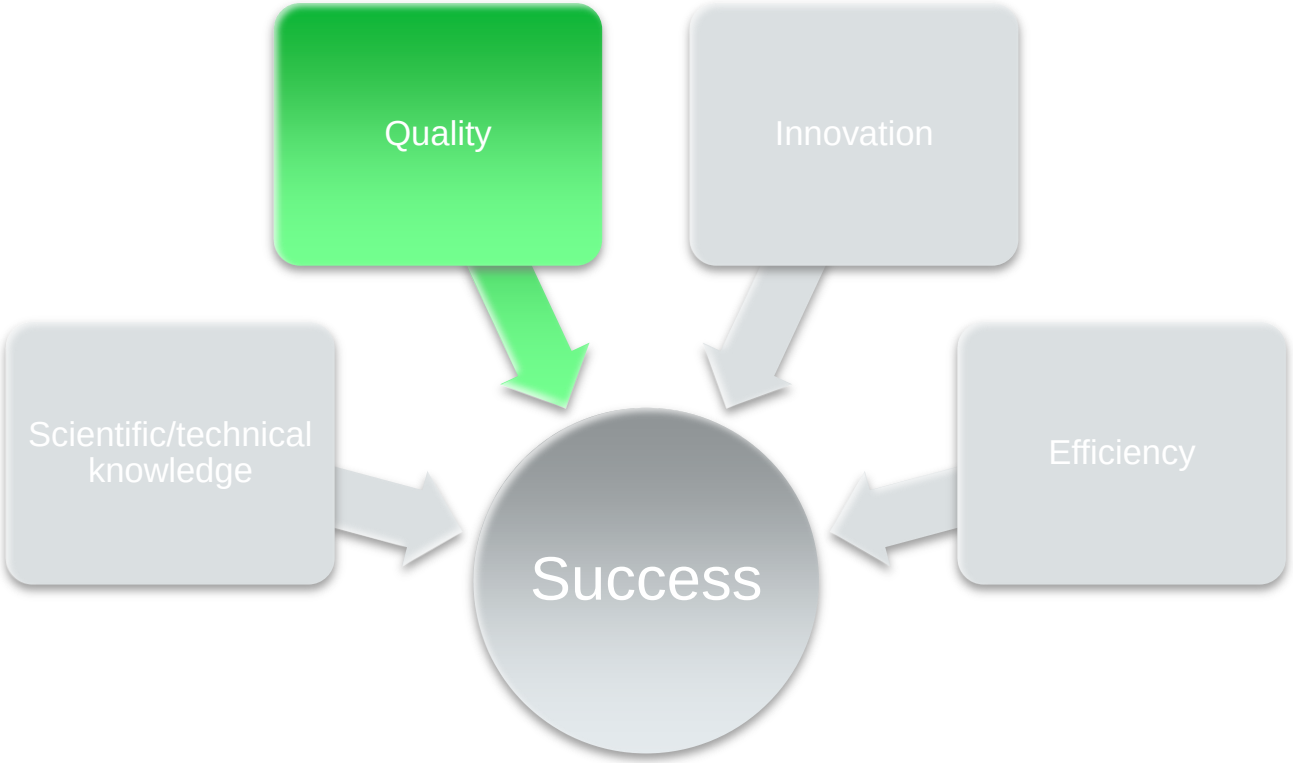

REGULATORY ENVIRONMENT: THINKING GLOBAL

Agenzia Italiana del Farmaco
AIFA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ICH

MHRA
Regulating Medicines and Medical Devices

FDA

CFDA China Food and Drug Administration

ANVISA

UNMET NEED (or partially covered)

Awareness

- of main regulatory agencies
- of type of existing guidelines -> where to look for, what to look for

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REGULATORY ENVIRONEMENT GMP, GCP…

UNMET NEED (or partially covered)

Awareness

- of meaning of the regulations
- of impact on ways of working

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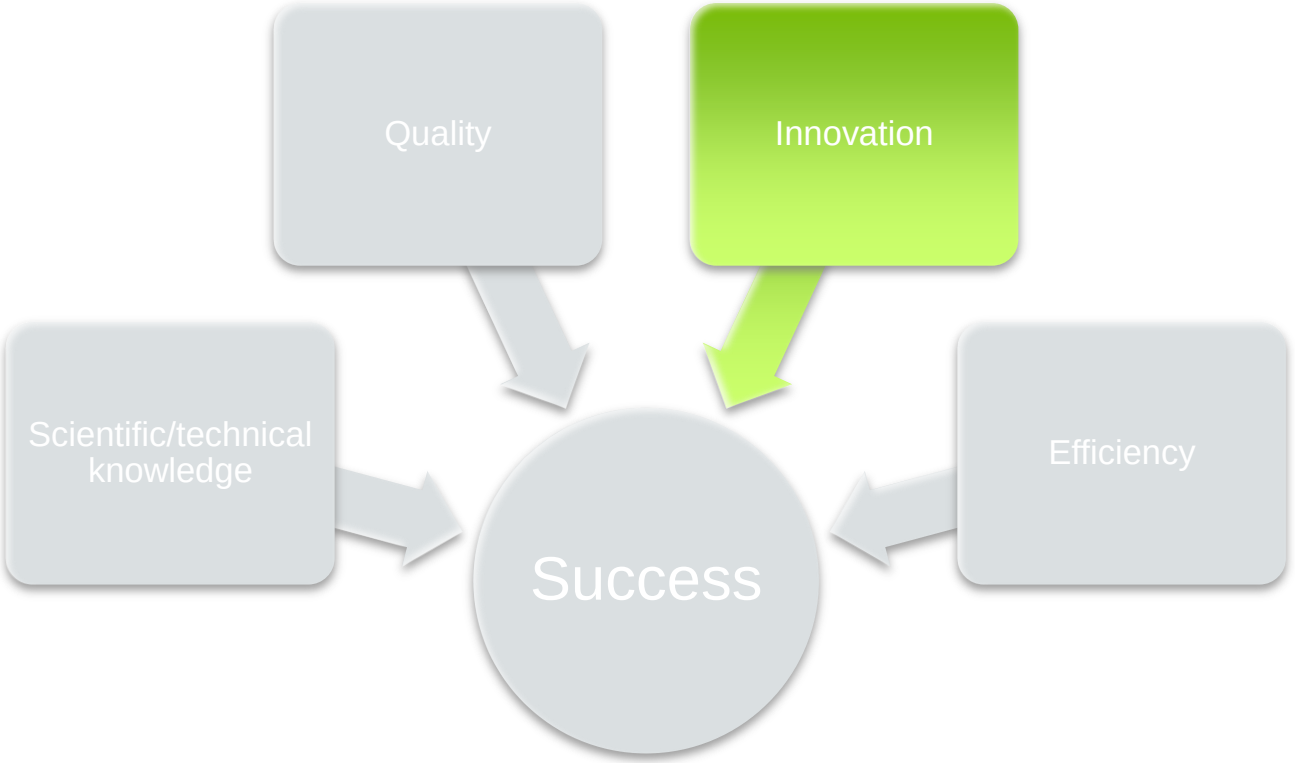
WHICH ARE THE PHARMACEUTICAL COMPANY (MAIN) NEEDS



PHARMA WORLD = ECOSYSTEM

…Again, a matter of **awareness…**

- Pharma world is changing with impressive speed, considering also the contribution of other technologies that can contribute to the change of the pharma world
- Core is the drug, but a lot of additional competences are required
- We need to know multiple languages: «digital», «informatics»…. for example

SCIENTIFIC ENVIRONMENT

- PARTIALLY COVERED NEEDS
  - Ability to find sources of information:
    - Papers
    - Patents
    - All accessible information
  - Deal with scientific information
    - Scientific language (English!)
    - Scientific methods

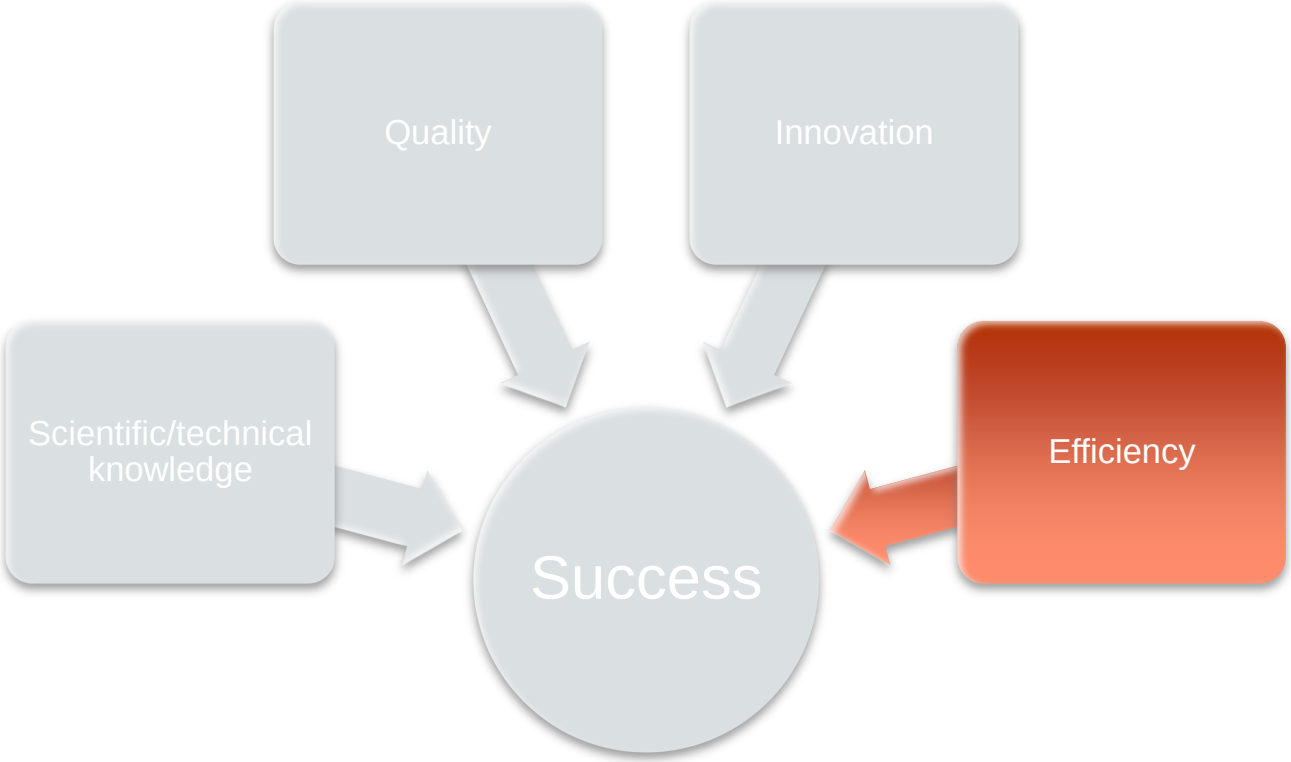
IN SILICO TRENDS

- UNMET NEEDS:
  - Awareness of:
    - Modelling
      - Process development
      - Interactions drug vs phisiological target
      - Predictive PK behaviour
      - ……..
    - Artificial intelligence
      - Possible application
  - Pharmaceutical background students are not engineers, but they need to deal with these topics!
    - Understand the background
    - Be able to challenge engineers!

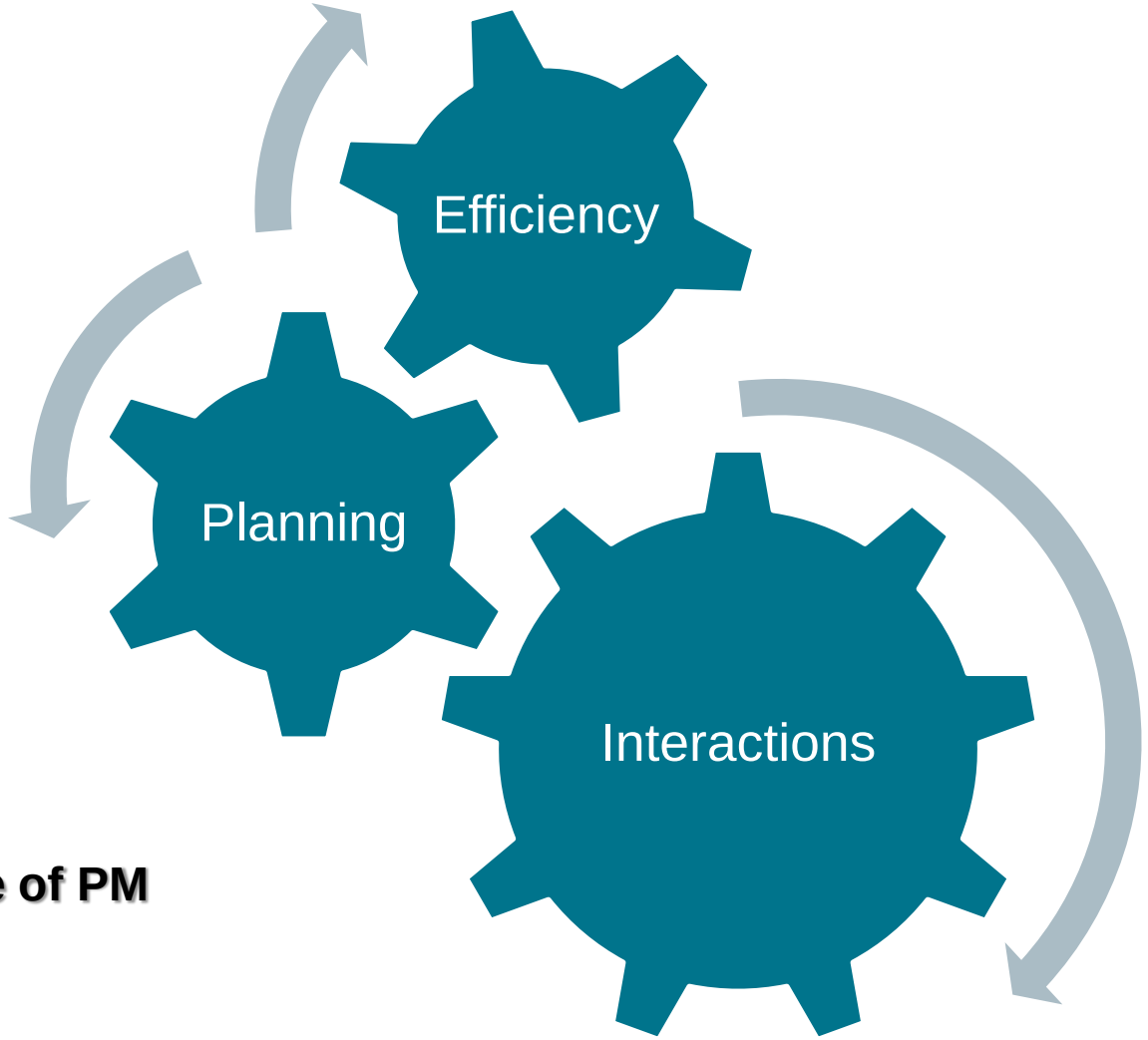
DATA MANAGEMENT

- Big data from Wikipedia:
  - **“Big data** is data sets that are so voluminous and complex that traditional data-processing application software are inadequate to deal with them. Big data challenges include capturing data, data storage, data analysis, search, sharing, transfer, visualization, querying, updating, information privacy and data source.”
- UNMET NEEDS:
  - Statistics to manage and digest big data and big data set
  - Basic of informatics

WHICH ARE THE PHARMACEUTICAL COMPANY (MAIN) NEEDS



PROJECT MANAGEMENT



UNMET NEED:
Basic knowledge of PM

WHICH ARE THE PHARMACEUTICAL COMPANY (MAIN) NEEDS

APPROACHES:Quality By Design

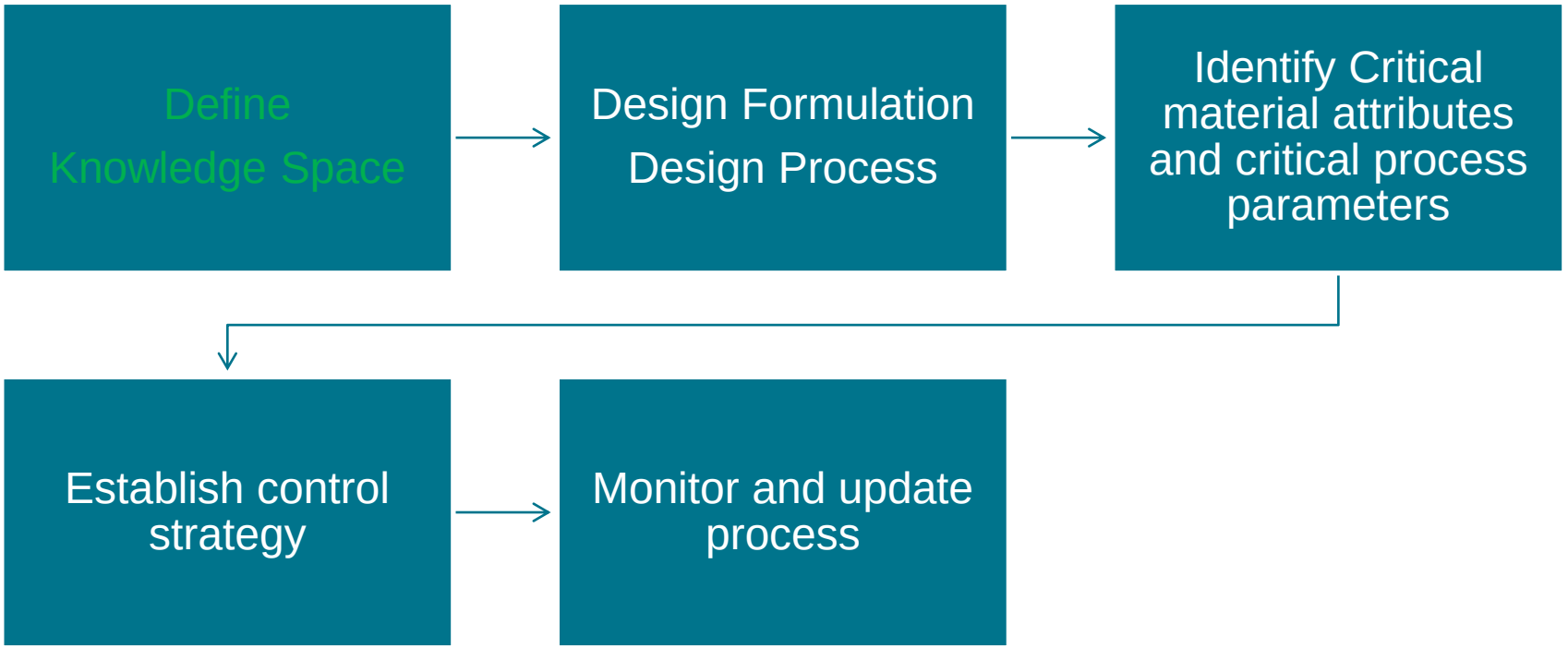
Quality by Design: Concepts for ANDAs
Robert A. Lionberger, Sau Lawrence Lee, LaiMing Lee, Andre Raw, and Lawrence X.
AAPS J. 2008 Jun; 10(2): 268–276.

- "FDA's emphasis on quality by design began with the recognition that **increased testing does not improve product quality** (this has long been recognized in other industries). The following equation indicates where quality comes from:
- Pharmaceutical Quality =

  f (drug substance, excipients, manufacturing, packaging)
- **In order for quality to increase, it must be built into the product**. To do this requires understanding **how formulation and manufacturing process variables influence product quality**; this is the function *f* in the equation above"

Quality by design

Given a Target Product Profile, depending on the clinical needs, we need to:



Tools: Design of experiment, risk assessment, Process analytical technologies

=UNMET NEEDS

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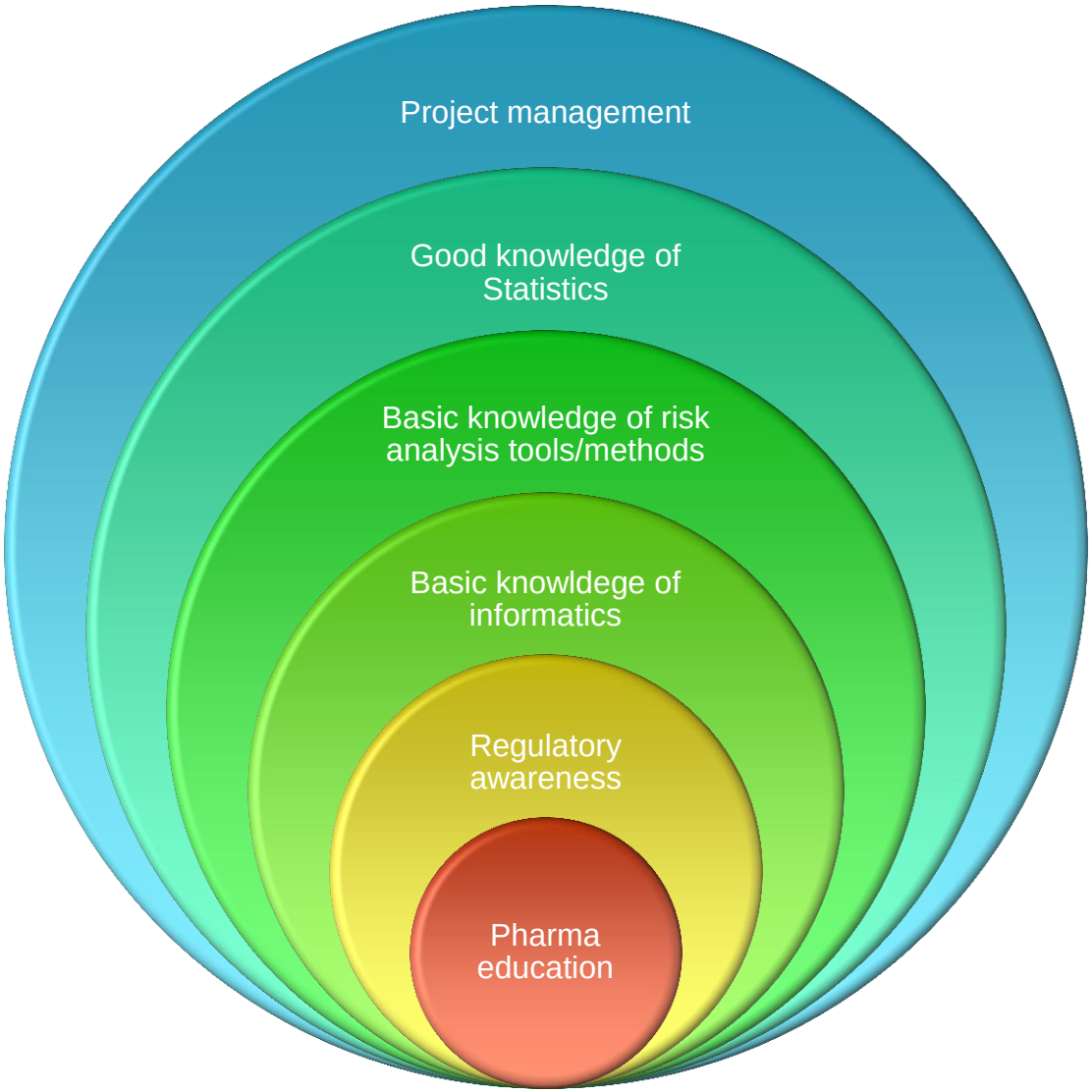
NEW POSSIBLE PROFILE FOR A RESOURCE IN PHARMA (with pharmaceutical background)



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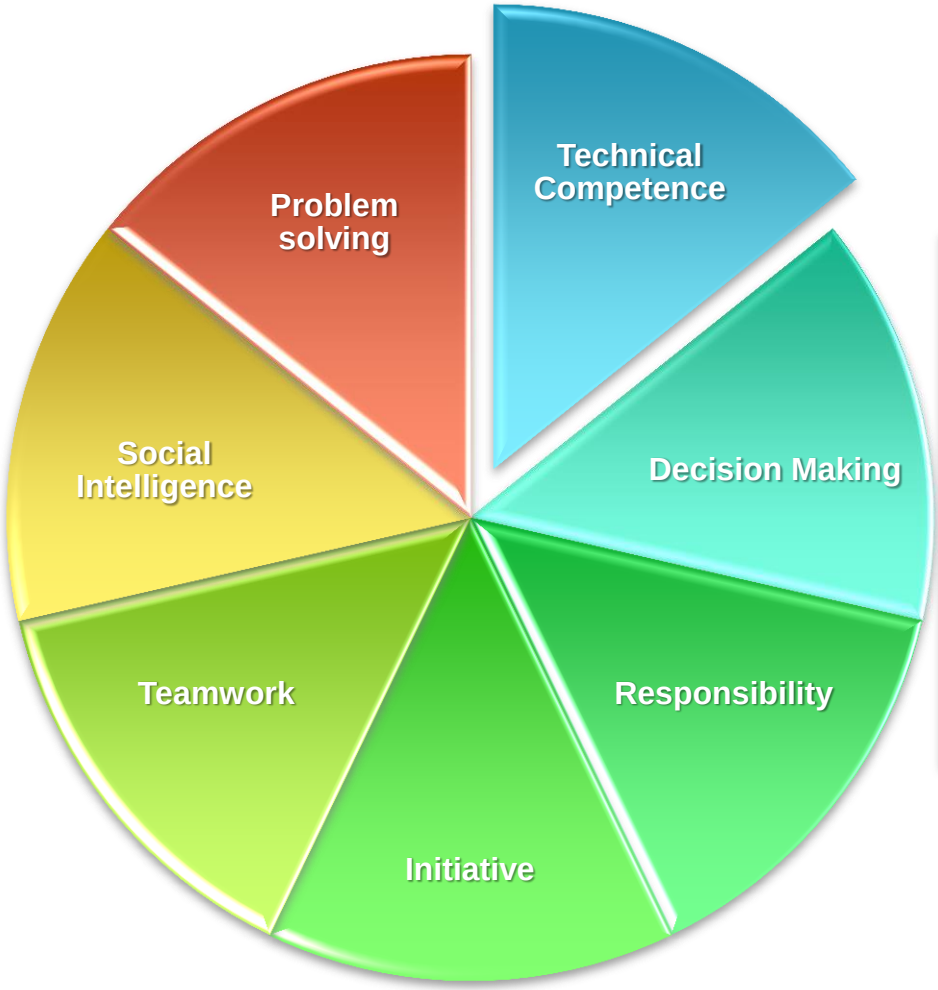
BUT DON' T FORGET…



Work is not only technical activities, There is a lot on soft skills exercise!

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CONCLUSIONS

- Help the growth of miscellaneous profile
- Encourage curiosity, openness and flexibility
- Be new «animal» in a new and broader «ecosystem»