Job opportunities in Clinical Research Quality Management

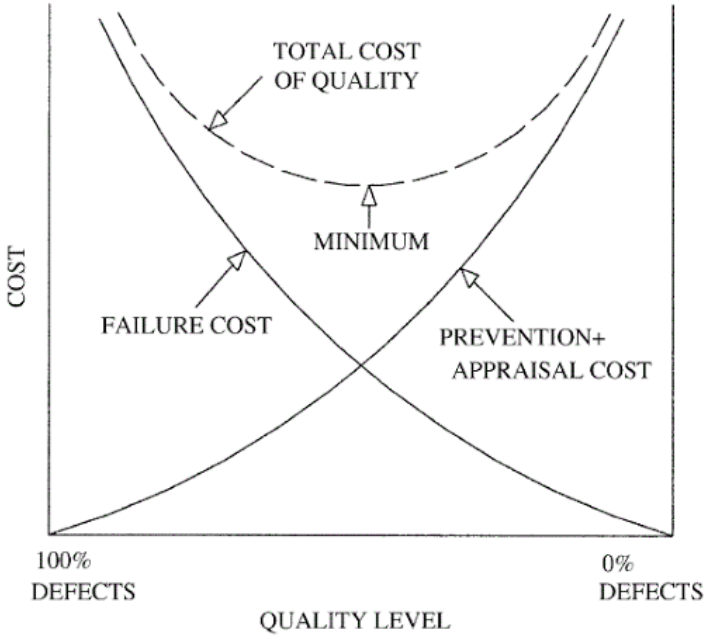
December 14, 2020

Iris Gorter de Vries, Director of Quality Assurance at SGS Life Sciences, Mechelen, Belgium

Disclaimer: the following is my personal opinion and not necessarily that of SGS

Quality in Clinical Research

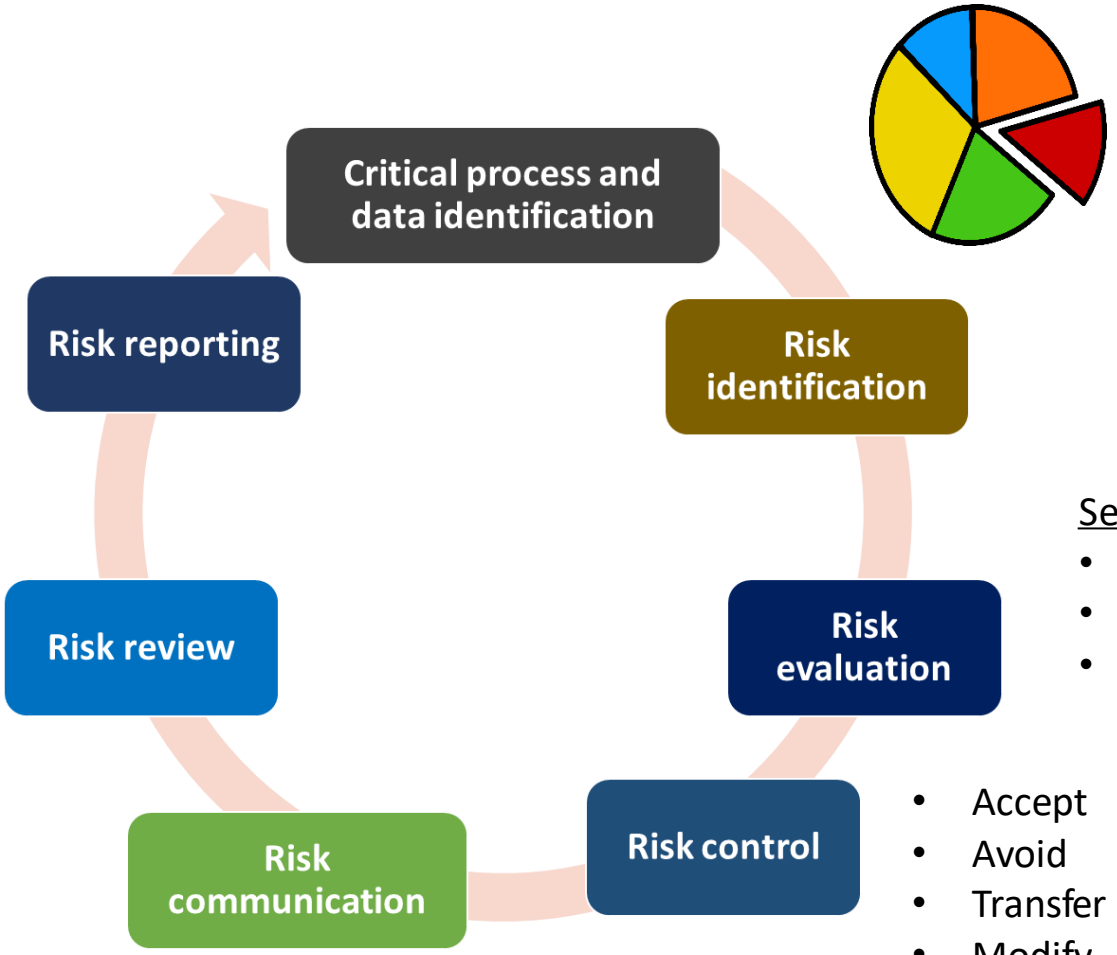
- Quality means of course Good Quality, but what is Good?
- Good Quality is the absence of errors that matter
- Level of quality defined up-front, with quality tolerance limits
- Good Quality is a requirement for all operational activities
  - Processes, staff selection, staff training, oversight of activities
  - Quality control - built into the processes



Quality in Clinical Research

- Quality in CR has 2 pillars
  - **Subject** safety
  - **Data** credibility
- **Subject**: healthy volunteer or patient volunteer
  - Safety, rights and wellbeing of the individual participant are protected
- **Data**: clinical trial data
  - Can be trusted in order to make sound decisions for market approval of medicinal products

Quality management : risk based



Seriousness

- Likelihood
- Detectibility
- Impact

- Accept
- Avoid
- Transfer
- Modify

Quality in CR is translated into Compliance with Guidelines and Regulatory Requirements

- **I**nternational **C**ouncil (regulatory authorities and pharmaceutical industry) on **H**armonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

- ICH-GCP (Good Clinical Practice)
- ICH-GXP (Good other Practice : GPV, GMP, GLP, GDP)

- Translated into international and national laws

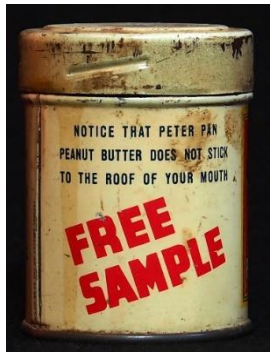
- Compliance is a prerequisite for market approval

The Challenge of Data Integrity

- Enormous Increase in Technological Capabilities
  - Computerized systems
  - Electronic records
- Increased Risks for Integrity of Data
  - Loss of context
  - Unnoticed and hidden changes to data
  - Unauthorised access to systems
  - Loss of data transitioning between systems
  - Data not retrievable (changes of hardware or software)

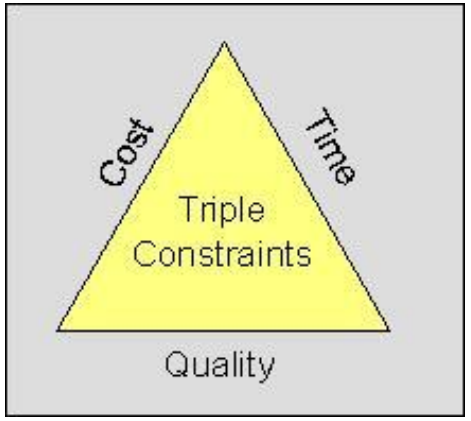
Roles in Quality Management – Pharma, CRO, Investigator Site, Institutions

- Regulatory Affairs: interaction with Regulators
- Quality and Compliance
  - Advice to the business, review of procedures
- Operational Quality Controller
- Author of Standard Operating Procedures
- Management of deviations: Root Cause Analysis, CAPAs (corrective actions and preventive actions)
- Computerized System Validation
- Information security management
- Quality Assurance (QA) : auditor
  - Independent of operational activities
  - Sampled approach
- Assessment of submissions for market approval: Government
- Assessment for funding: Institutions; Banks



Background and Challenge

- Background in medical sciences, medicine, medical devices, pharmacy, pharmacology, nursing, laboratory techniques, computer science
- PhD not required; language abilities important (English)
- Understanding of clinical research is important, but can be learned ‘on the job’
- Quality minded
- Challenge: balance the requirements from Quality and Regulatory point of view with those of the operational teams who have to deal with
  - complex situations
  - short timelines
  - tight budgets



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Thank you for your attention