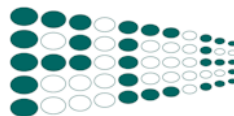
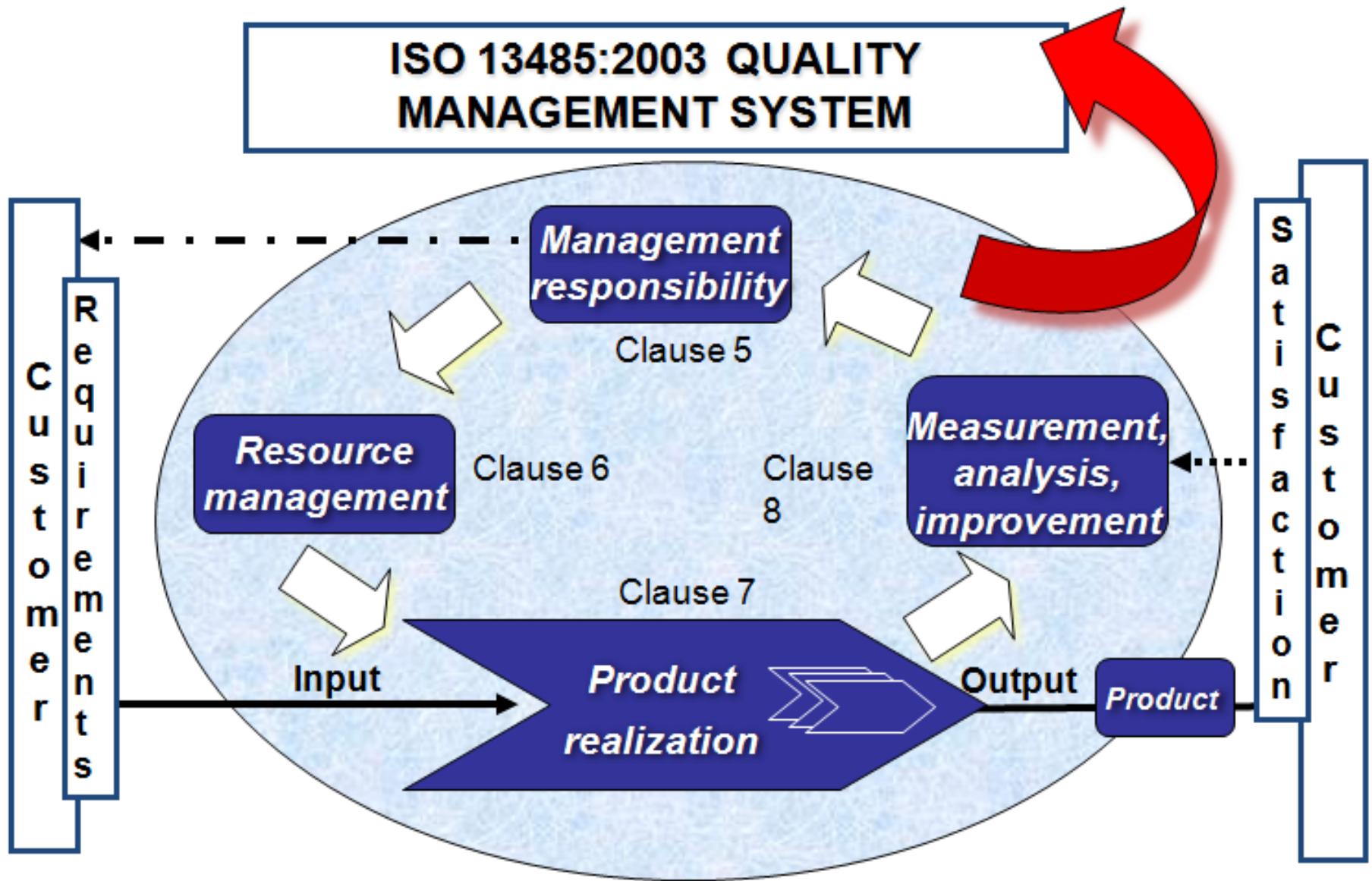


# ***Management Review***

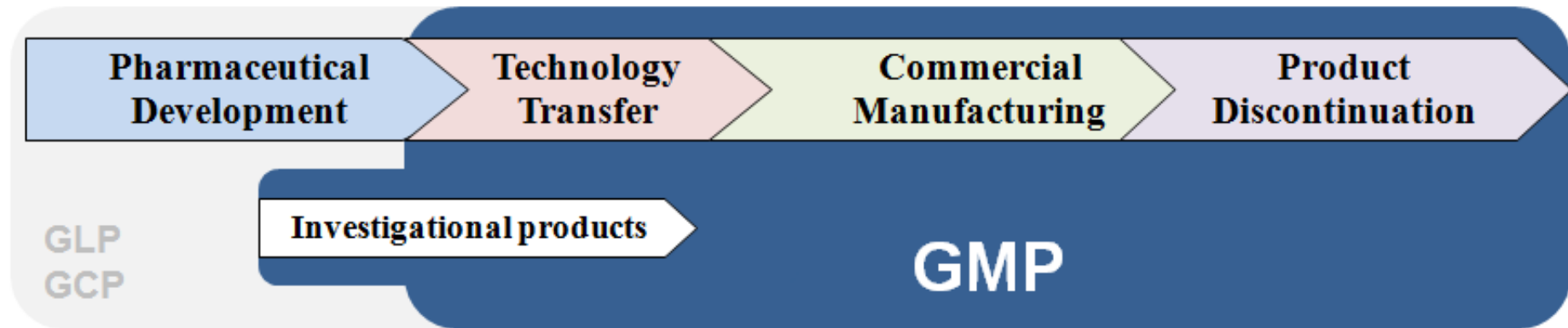
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2851 VV Haastrecht, the Netherlands  
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# ISO 13485:2003 QUALITY MANAGEMENT SYSTEM



# Q10 Life Cycle & Management Involvement



## Management Responsibilities

### PQS elements

Process Performance & Product Quality Monitoring System  
Corrective Action & Preventive Action (CAPA) System  
Change Management System  
Management Review

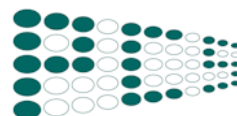
### Enablers

Knowledge Management

Quality Risk Management

# Basics

1. Develop/Improve workflows which includes Data Gathering for Management
2. Agreement on settling the program for a one harmonised System for Managing Quality, throughout sites
3. A charter for the roll-out of implementing a Monthly Quality Report with KPI's (takes long)
4. Developing a common level of understanding on key topics.
5. Focus and include in data gathering the requirements for PQR(APR) and Pharmaco - vigilance.





Product

Organisation

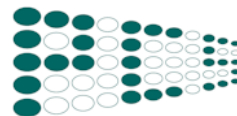
ENVIRONMENT  
(Market, Regulatory, ...)

Mngmnt

# Quality Management Expectations

## The Quality System should support or promote:

- Latest insights on Quality Management as expressed by ICH and according WHO
- TEAMWORK within the entire Quality Department of Panacea/Panera,
- A PRACTICAL approach
- An efficient and effective ORGANISATION for:
  - delivery and/or development of (investigational) medical products.
  - performing clinical studies
  - according LICENSES and/or guidelines by the competent authorities,

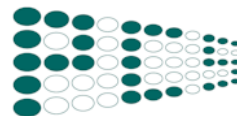


# Quality Management Expectations

## *Continued*

### The Quality System should support or promote:

- **FOCUS** on the burning (Quality) issues of today and solve those both organisationally and intrinsically,
- **Data-, knowledge and risk driven (PRO)ACTIVE ACTIONS** in correspondence with severity of adverse quality trends or issues,
- The rationale for setting quality driven **EXPECTATIONS** and **PERFORMANCE** requirements,
- A focus on settling **Tasks, Responsibilities and Authorities** per group or per individual.
- **THE BUSINESS OF Panacea/Panera**





Product

Organisation

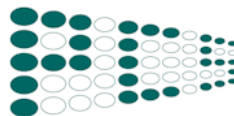
ENVIRONMENT  
(Market, Regulatory, ...)

Mngmnt

# Management Review

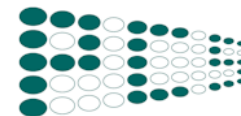
Review of Quality Systems with KPIs (examples given:)

- Complaints
- Recall – by exception
- Internal audits
- Inspections of outside agents
- Deviation trends
- Stability
- Additional (> PQR)
  - Change control
  - OOS
  - Vendor management items



# COMPLAINTS / RECALLS (Examples)

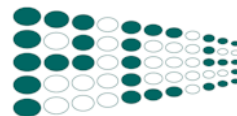
Quality Item	Performance indicator	Reporting frequency
Recalls	Occurance, product, market	By exception
Complaints	Total# up/down per manufacture site	Monthly
	Total up/down <i>per sales</i> per product (category) per country/markets	Monthly
	# Adverse Events (up, down, category)	Monthly
	Closure on time	Monthly
	Root-causes (category) Re-occurrence Trends	Quarterly
# = number	(upcoming) issues	Monthly (as needed)



# INTERNAL AUDITS (Examples)

Quality Item	Performance indicator	Reporting frequency
Internal audits	Adherence to plan, # scheduled and # performed	Quarterly (due to number and freq of audits)
	# Major and minor findings	Monthly
	Closure of CAPA / finding on time	Monthly
	(upcoming) issues	Monthly (as needed)

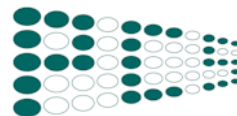
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# INSPECTIONS (Examples)

Quality Item	Performance indicator	Reporting frequency
Inspection findings	# Major and minor findings	Monthly
	# Findings closed, open, open overdue	Monthly
	(upcoming) issues	Monthly (as needed)

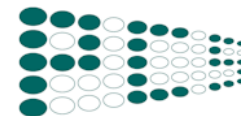
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# EXTERNAL AUDITS / VENDOR MANAGEMENT

Quality Item	Performance indicator	Reporting frequency
External audits	Adherence to plan (all sites combined)	Quarterly (due to number and freq of audits)
	# CMO's, API, others not audited	Quarterly
	Critical observations made number and closure	By exception
	(upcoming) issues	Monthly (as needed)
Vendor management	# Complaints on raw materials per supplier, per category	Monthly
	# CMO's, API, others Quality Agreement in place	Monthly
	(upcoming) issues	Monthly (as needed)

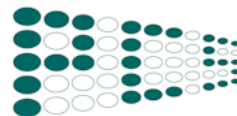
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# DEVIATIONS (Examples)

Quality Item	Performance indicator	Reporting frequency
Deviations	# deviations per site per category	Monthly
	# or % of failed batches per site	Monthly
	Root-causes (category) Re-occurrence Trends	Quarterly
	Closure on time of CAPA	Quarterly
	(upcoming) issues	Monthly (as needed)

# = number

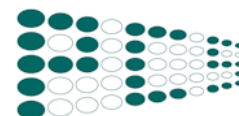


# ON-GOING STABILITY (Examples)

Quality Item	Performance indicator	Reporting frequency
Ongoing stability	Adherence to plan	Monthly
	OOS	Monthly*
	Expiry date confirmed Trends Per product(-group)	Quarterly
	(upcoming) issues	Monthly (as needed)

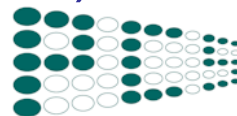
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\* = should be reported to management as soon as possible (< one month)



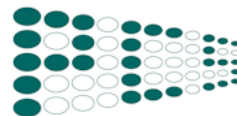
# Summary (QMS Review)

- Provide senior management an overview of quality performance
- To show trends across the sites
- Show critical areas where improvements can be made, possible investigations required and assist in prioritisation
- Prevent Regulators finding issues
- Meet requirement of Quality Management system requirements for continuous improvement (ICH Q10)



# Product Quality Review

- Analysis of product performance
- As an example check Pharmacovigilance with Process Validation
  - If you see adverse trends (e.g. Complaints) how can that have been missed by your Critical Parameters ?
- Need to set-up a system to catch the details and reporting system, alike with former slides concerning KPI's
- Work-flows: if multiple sites are involved in product: how to organize and who will be responsible (Corporate ?)



# Management Review (suggestions)

- Start simple
- As an example, start with a limited amount of KPI's
- Organize a Monthly Meeting with senior Quality People to discuss reporting system.
- Organize a Quarterly Meeting with senior Management
- Communicate backwards and forwards (need to be included in the design)
- Be disciplined and work with a program when to implement what.
- Keep still your eyes open for negative trends and react on that.
- Still: it might be systematic, it needs human's attention.
- **Document** (notes/minutes/letter-to-file/...)

