



#sharing challenges
and solutions in practice

Reinventing the wheel

Current manufacturing compliance and efficiency trends and their implementation

Conference

Part of PharmaCongress – Düsseldorf/Neuss, 31 May–1 June 2022

MANDATORY

PURPOSEFUL?

HINDERING?

COMPLIANCE!

Compliance and Business Success



Risk Identification and Mitigation

Corrective & Preventive Actions

Safety & Effectiveness of Processes

Quality

Excellence

Process Automation and Controls

Data Integrity

Efficient Utilization of Resources

Operational
Excellence

The Inflection Point

“Quality-by-Inspection” towards “Quality-by-Design”

Compliance

- Requires dedicated costs and efforts
- Mandatory to business
- Reactive mode of activities

Traditional

VS

Foresightful

- Seamlessly integrated in operational processes
- Strategic contributor to business success
- Able to anticipate & prevent adverse quality events

...and Digitalization for all.

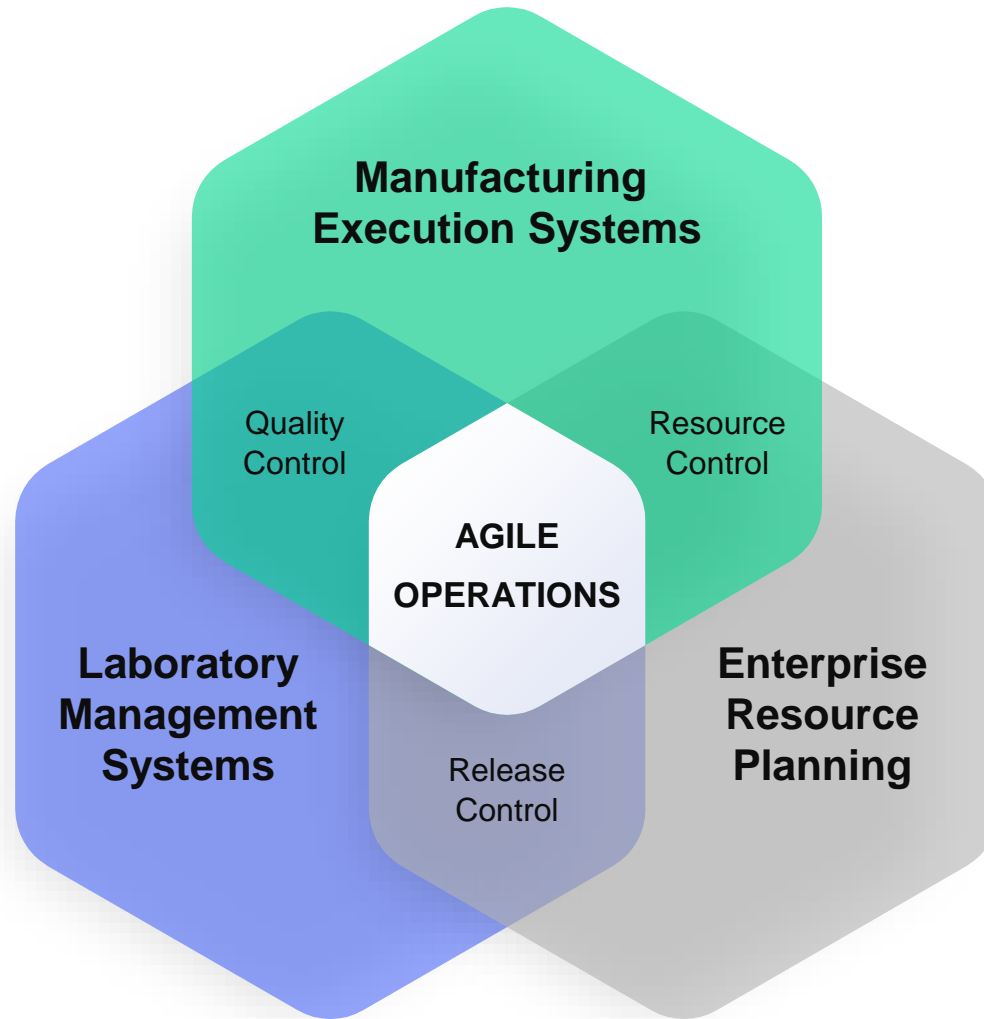
Efficient tracking & trending

Automated processes

Benchmarking of best practices

Sustainability

Customized solutions



Improved Data Integrity

Efficient review & release

Global visibility of data

Upgraded functionality

Transparent KPIs

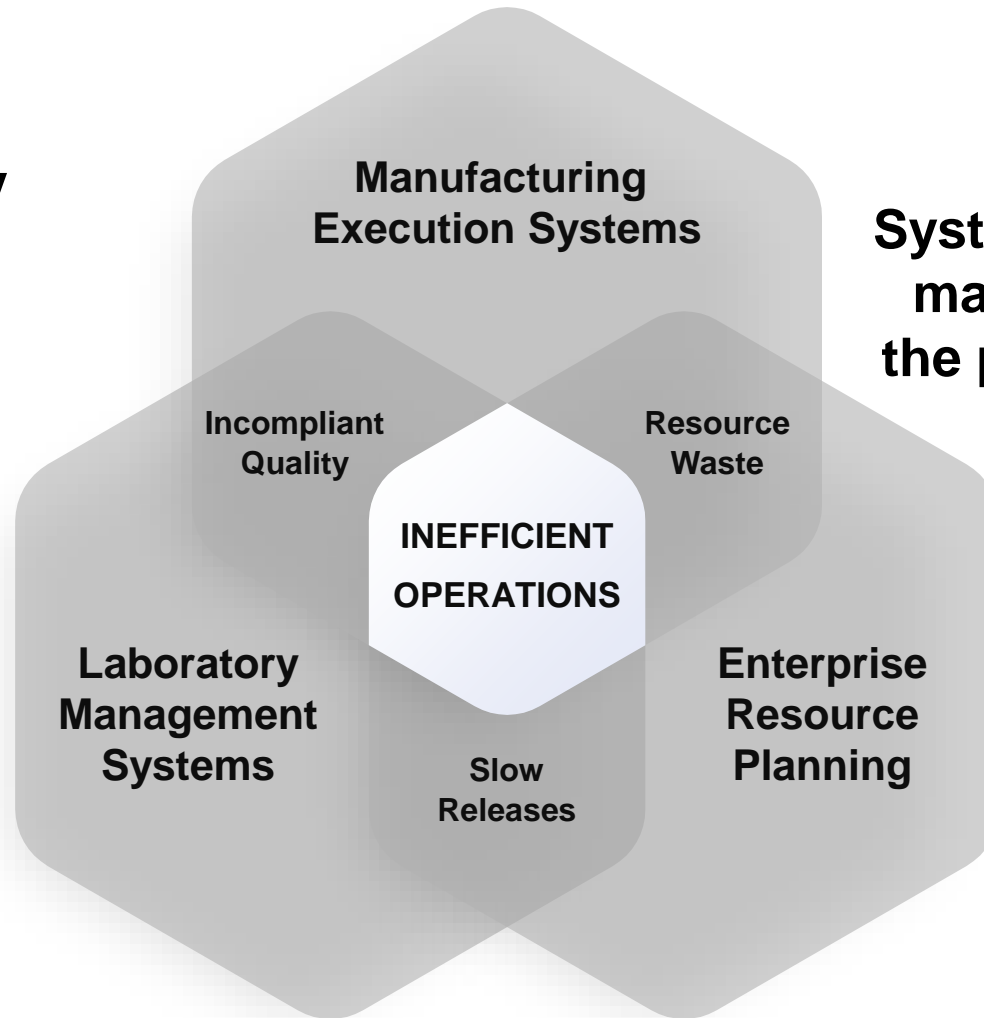
Taking the red pill.



Data Integrity issues

Systems talking different languages

Plenty of human interaction



Systems not matching the process





Fragmented data



Lacking resources

How can we get there?

DO THESE

-  1 Use a **Single Source of Truth**
-  2 Have a **central planning**
-  3 Have **seamless track & trail**
-  4 **Real-time data** collection & comparison

Do **siloed process design**

1

Over-automate

2

Go digital **without a working process**

3

Try to **put the world under compliance control...**

4

DON'T DO

Thank you for your attention

QUESTIONS ?