Managing Post Approval Changes:
yesterday, today and tomorrow

2015 PDA Manufacturing Science Workshop

Pierre-Alain Ruffieux, PhD

Head of Novartis Pharma Quality

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The journey starts with a need for change ...

Trigger

7th May 2014

Trigger

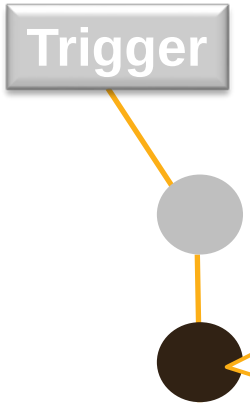
Initiation

Change Request Initiated

Setting of :

- ☑ Current testing site
- ☑ Proposed testing site for release & stability
- ☑ Justification
- ☑ Record in internal systems

10th July 2014



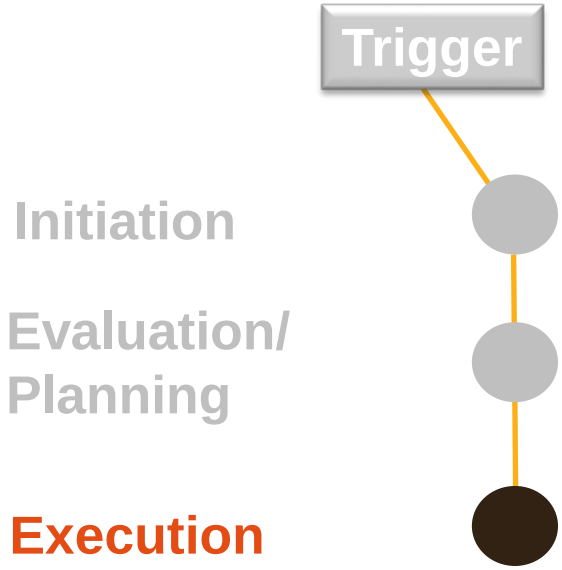
Initiation

Evaluation/ Planning

Change Request Evaluation Complete

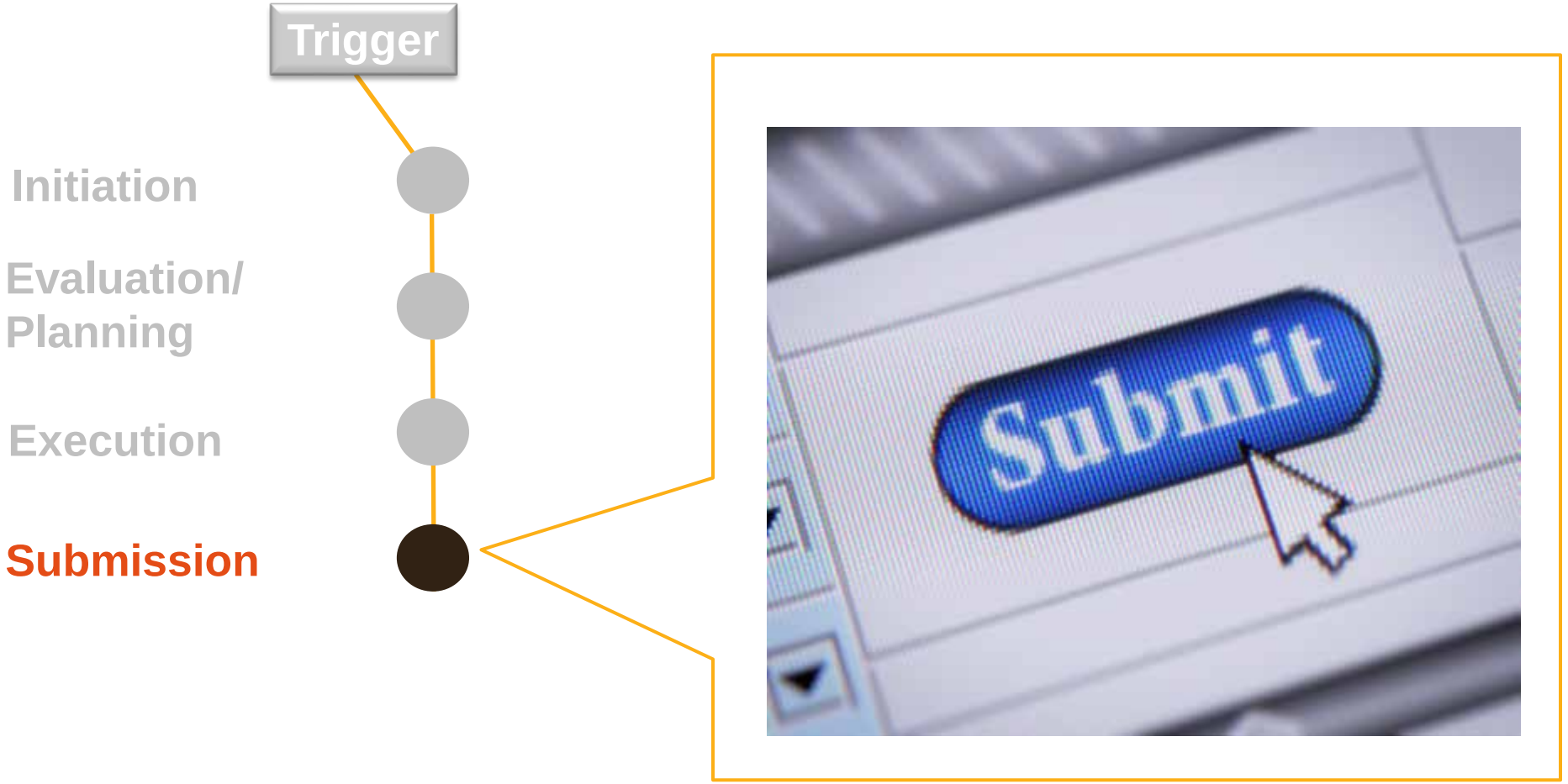
- ☑ GMP status: Site not FDA Approved that requires successful FDA inspection therefore classified as **Post Approval Supplement (PAS)**
- ☑ **CTD** Module ‘Manufacturers’ to be updated
- ☑ Highlight need to complete method transfer prior to submission

5th December 2014

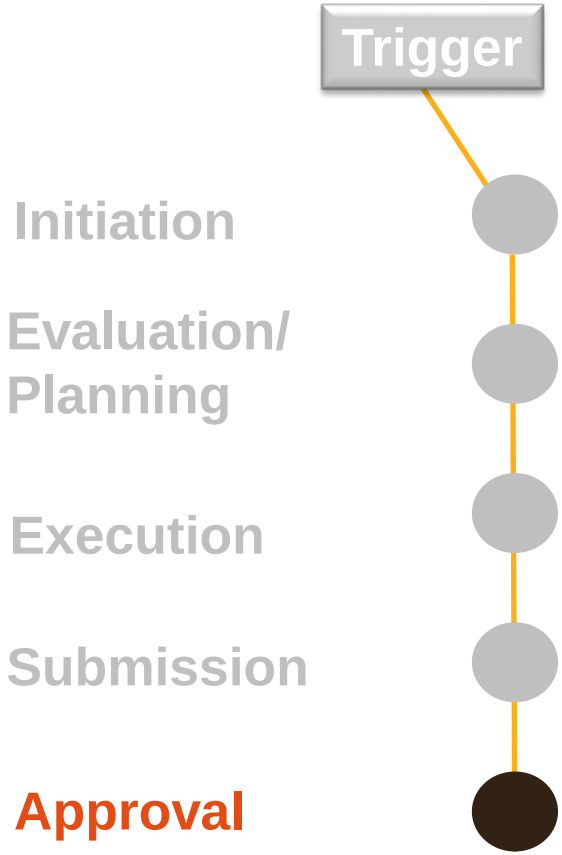


- ☑ Method Transfer executed & approved
- ☑ Preparation of documentation for dossier update

15th December 2014



After 11 months the journey ends ...



After a successful FDA inspection in 1st week of April, approval was received.

...with the change implemented.

Starting from 15-Apr-2015:
new set up in use

☑ Implementation of the change


LOOKS EASY AS PIE DOESN’T IT?

This is not as simple as it looks because....

1 Highly regulated industry

This is not as simple as it looks because....

1 Highly Regulated Industry

2 The requirements are different from country to country

This is not as simple as it looks because....

1	Highly Regulated Industry
2	The requirements are different from country to country
3	Approval & implementation timelines are different from country to country

130+

marketed brands

700+

submissions packages dispatched per year to countries

14,000+

submissions per year to country Health Authorities

140+

countries supplied

10,000+

stock keeping units


LEARN
FROM YESTERDAY
LIVE
FOR TODAY
HOPE
FOR TOMORROW

What we've learned...

1 **Yesterday**

2 Today

3 Tomorrow

- Data was maintained across multiple systems which required very high level of knowledge to either use or maintain the data
- Change control process was fragmented
- Focus of the workflows was more on correct handoffs between line functions & information

What we've seen...

1 **Yesterday's Challenge**

2 Today

3 Tomorrow

As a consequence there was:

- risk of non-compliance
- low incentive to make more changes

Based on yesterday's learnings ...

1 Yesterday

2 Today's fit for purpose

3 Tomorrow

- A robust system that enables Pharma companies to manage all changes during the life cycle of a product

Every project has its challenges ...

1 Yesterday

2 **Today's Challenge**

3 Tomorrow

- Need to build a new system to unify complex information systems & fragmented processes
- Data migration could disturb ongoing changes
- Requires investment (people & money)
- Requires broad retraining & refining

What we're implementing

1 Yesterday

2 Today

3 Tomorrow

- Robust & exact process
- Accuracy & completeness of data
- Easy tracking
- Clear roles & proper involvement
- Clear timelines

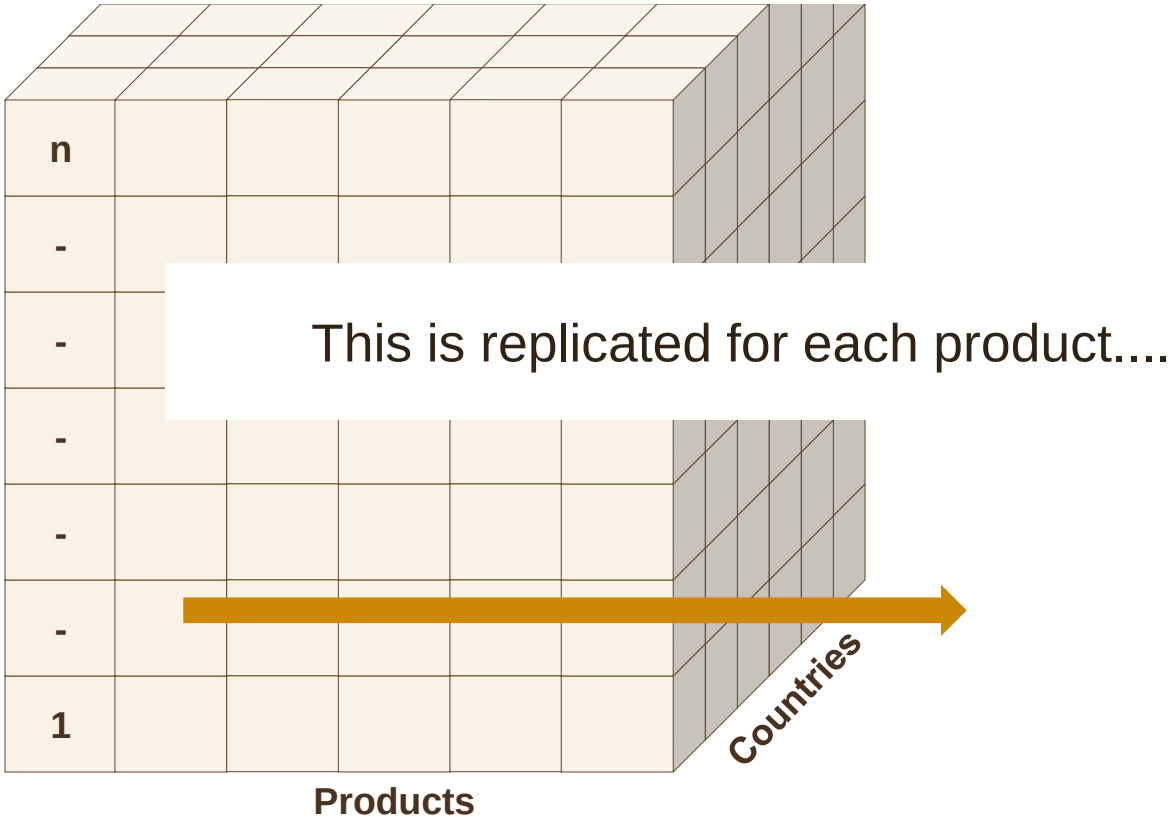
We want to....

- Quickly **adapt to new demand & business**
- Have the **regulatory relevant product data** managed in a **single information system**.
- Have an **easy overview** on all **product lifecycle events** in a **single information system**
- **Correctness** & Usability/Learnability
- Ensure **Integrity** & **Reliability**
- Enhance **Efficiency** & **Security**

Let’s have a closer look...

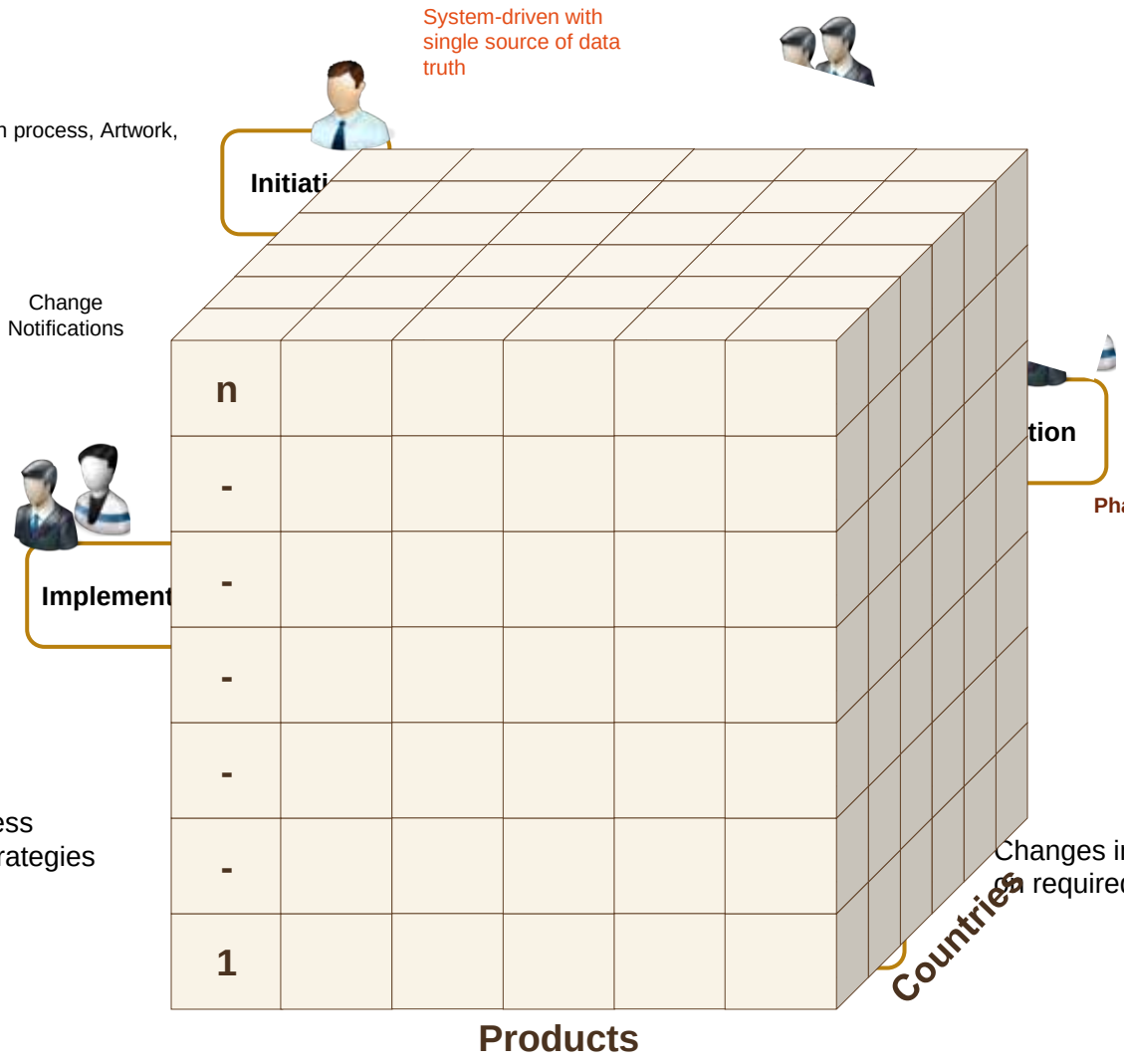
...and this is multiplied by number of

The n regulatory relevant information for **one product** is stored as follows....



This is replicated for each product....

we've implemented a fixed workflow process...



Closed loop change implementation with notification back to requesting initiator

The authorization process captures submission strategies

Changes in parallel or consolidated based on required implementation schedules

Clear benefits on the execution...

Increase **ACCURACY** of data & **EFFICIENCY** of data maintenance

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Increase **PREDICTABILITY** & **SPEED**

in implementation of Product Lifecycle events

Increase **CAPABILITY** of the organization & **FLEXIBILITY** to handle new demand and business growth

What the future could hold...

1 Yesterday

2 Today's fit for purpose

3 Tomorrow

Our hope for a bright future...

1 Yesterday

2 Today's fit for purpose

3 Tomorrow

- One common standard facilitating submission of a single harmonized package globally
- Enabling the move from control based bureaucracy to knowledge-based management of the changes
- Risk-based approach and the possibility to manage minor changes through company's Quality Management System

What would be our hope for tomorrow...

1 Yesterday

2 Today's fit for purpose

3 **Tomorrow's Challenge**

We still need to ensure collaboration between industry, regulators & patient associations

What is ongoing...

ICH Q12 should facilitate predictability & efficiency of post-approval change management, thus supporting innovation and ensuring sustained product supply.

In conclusion

Post Approval Change is a relatively simple process on the surface...

... but requirements vary significantly from country to country in terms of reporting levels, amount of documentation and approval timelines.

This represents a significant barrier to continuous improvement & a challenge in maintaining compliance...

....ultimately potentially impacting the capacity of the industry to deliver products to patients.

IT systems can facilitate the variability of the process but don't remove the regulatory complexity....

In conclusion

We aspire to move away from pre-approval “control-based” system to “science-based” knowledge where changes are implemented on a “tell & do” basis and reviewed during routine inspection.

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