Challenges for marketing and manufacturing authorization holder

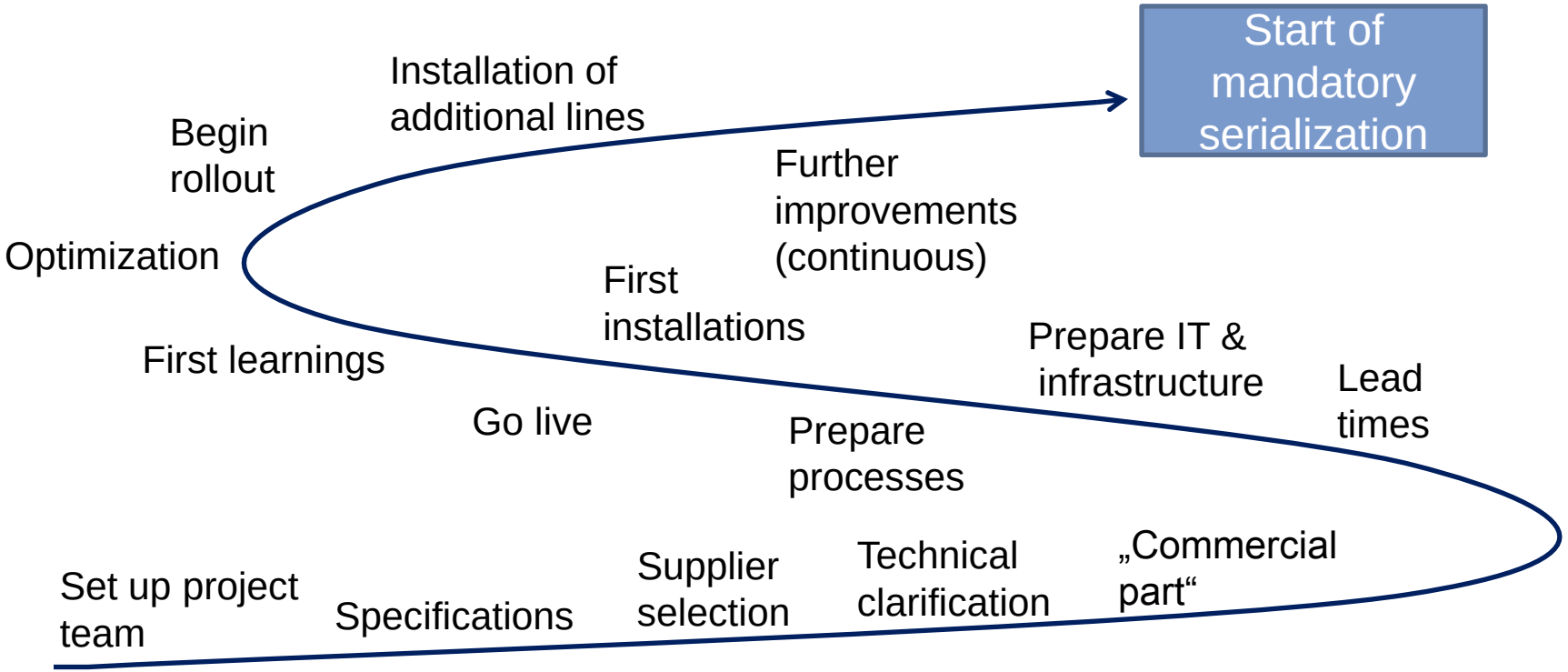
K. Egner, Merck KGaA

Overview

- How to implement the requirements of the falsified medicines directive in a pharmaceutical company
- Tasks, feasible timelines and who has to be involved

First Contact With Serialization

Serialization Step By Step



The Learning Curve: Installations…

- Installation of equipment and machinery at a packaging line takes time. It is often not easy to align the required downtime with production.
- Postponing can lead to issues because several parties must be available for an installation.
- Not all installations will proceed as planned, especially at retrofits. The reasons are the high complexity in combination with human factor.
- Every machine is different, so the „rollout“ will be more or less a series of (similar) projects.
- There are learning curves between system suppliers, machine suppliers and company IT, too.

…From Go live! To Regular Production…

- Everything organized from processes to SOPs?
- New packaging material available and released?
- **Enough operators trained?**
- → Go live date can be kept?

- Are production efficiency and capacity still the same as before?
- A certain learning curve is very common.
- First feedback from the market: **Did the overall process work?**

…From One Line To The Next

- Production lines most times differ in little details. Which of them have an impact on serialization is sometimes not obvious but surprising.
- Sometimes machines of the same type are very different.
- Relevant factors can be:
  - Speed of line
  - Packaging material (size, which tamper evident features possible?...)
  - Weight of product
  - Restrictions by product (e.g. orientation…)
- If there are major issues with a line or a product it can bind resources to a large extent. So it can influence the whole project.

Tasks (high level)

- Packaging lines: Implement **serialization** capabilities and equipment to support **tamper evident features**.
- IT Systems: Provide systems to handle and store serialization data. This includes interfaces make the required data available for the target system (EU Hub, PU-System…). In case of contract manufacturing appropriate considerations are necessary.
- Packaging material: Check and adapt packaging material for serialization and tamper evident features.
- Implement processes for the “life cycle” of serial numbers!

Feasible Timelines

- The exact time is company specific to a certain degree.
- The capacities of the established suppliers are limited, so lead times are now longer than some years ago.
- In most discussions 18 month seem to be the common estimation.

Whom To Involve

- Everyone!
- To meet the requirements of the FMD many cross-functional activities are necessary.
- Besides IT, engineering, production and QA, departments for packaging material and artwork should be involved early enough to avoid bottlenecks.
- The **operators** will have a special role, their training is key!

Conclusion

- Implementing the requirements of the FMD is a complex and cross-functional project. Good teamwork will be mandatory.
- A learning curve will be very common.
- A possibility to “practice” serialization before it is mandatory (like Securpharm) can be very helpful for a good transition.
- **It is important to start with implementation now**, time will be short enough.

securPharm

2. securPharm European Conference on the Falsified Medicines Directive

22.7.2015
for German pharmaceutical industry, wholesalers und pharmacies

23.7.2015
for international stakeholders