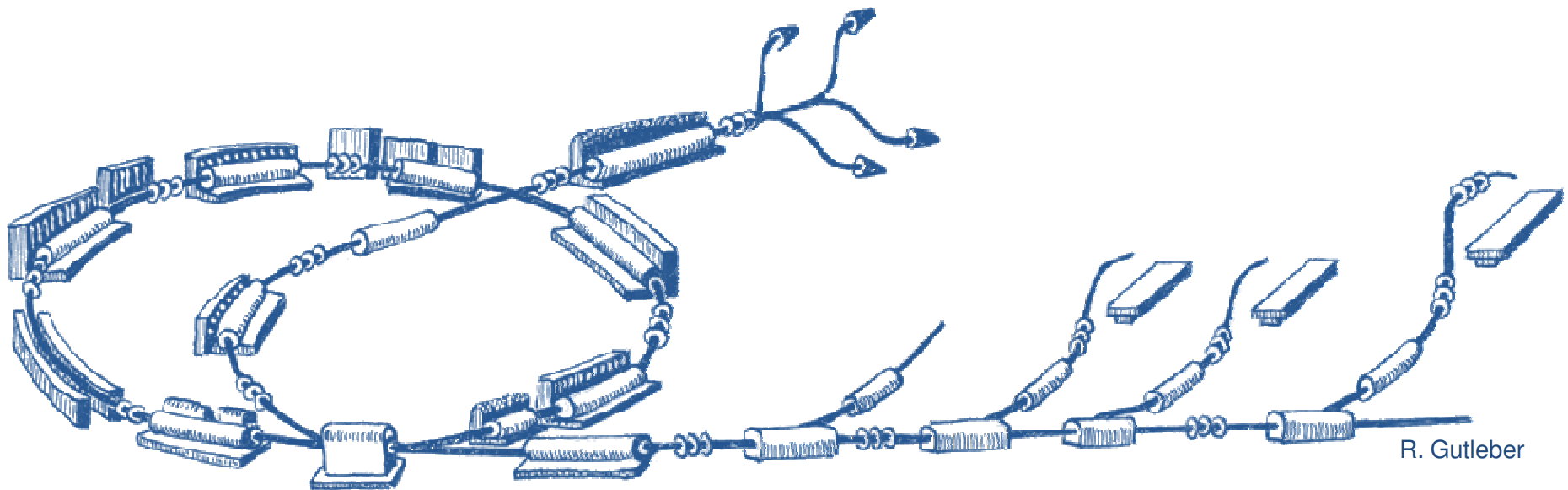


Work Package Controls

Inception Phase Review

February 5th, 2010

Johannes Gutleber



INTRODUCTION AND REVIEW SCOPE DEFINITION



Review Schedule

09:00 – 09:10 Welcome (MBE)

09:10 – 09:20 Introduction and scope definition (JGU)

09:20 – 10:10 WP controls high-level goals (JGU)

10:20 – 11:10 Development process presentation (JGU)

11:10 – 11:35 Configuration management environment (RMO)

11:45 – 12:20 Safety concept and scope (FMO)

12:20 – 12:45 Safety system outlook: interlock system (MMA)

Lunch Break

14:30 – 17:00 Closed review session

Goals of the Review

- Achieving agreement on **scope** of work package “controls”
- Achieving agreement on **development process**
- Acknowledging identified risks and achieving agreement on proper **identification of major risks**
- Achieving **agreement on high-level functions** of system to be developed
- Acknowledging and achieving **agreement of work organization and work** to achieve the goals

WP Controls Contributions

- Project documentation
- Summary presentations
- Q & A style additional information
- Review report distributed after review

Contributions from Reviewers

- **Identify open issues** that would prevent advancement to the next project phase (elaboration phase).
- **Propose mitigation actions** on the risks identified.
- Help to **refine scope** of the work package
- **Assess realism** of current project development setup
- **Give recommendations**
- **Point out corrective measures** on the next steps

Expected for Milestone

- Defined work package scope
- Agreement with other work packages on scope
- Cost and schedule estimated
- Project risk management process defined
- Major risks identified and acknowledged by top management
- Parameters from existing processes and designs identified
- Project environment defined
- Initial requirements defined
- Project plan defined
- Project plan aligned with top management
- Development process defined and accepted
- Medical device safety concept/scope completed

Achieved at Milestone

- ✔ Defined work package scope
- ❓ Agreement with other work packages on scope
- ✔ Cost and schedule estimated
- ✔ Project risk management process defined
- ✔ Major risks identified and acknowledged by top management
- ✔ Parameters from existing processes and designs identified
- ✔ Project environment defined
- ✔ Initial requirements defined
- ❓ Project plan defined
- ❓ Project plan aligned with top management
- ✔ Development process defined and accepted
- ✘ Medical device safety concept/scope completed