



MEDICAL TECHNOLOGY

Risk Management in the
Development Process



Integration of RM* According to DIN EN ISO 14971 in the Development Process



From Requirements Management to the complete integration of Risk Management into the product development – PLATO has the solution for your development process of medical devices.

PLATO Design Control

Keep the overview of all your requirements – from the first idea to the final product.

PLATO Risk Management 14971

Prove that the benefit of your medical device is greater than its risk.

PLATO Technical Risk Management

Identify complex interactions and avoid expensive product recalls at an early stage in the product development process.

Your Benefit

- **The integration of Risk Management** in the development process promotes acceptance within the team.
- **Quick additions/changes** through central data maintenance and analyses.
- **Safety** through centralized action monitoring.
- **Effective knowledge management** through visual evaluations and data base analyses.
- **Shortened approval times** through consistent and current product data.

*Risk Management

	PLATO Design Control	PLATO Risk Management 14971	PLATO Technical Risk Management
Traceability of Requirements incl. V+V	•		
Systems Analysis	•		•
Requirements and Function Analysis	•		•
Specification (Design Input/Design Output)	•		•
Risk Analysis		•	
Risk Graph		•	•
Risk Governance		•	
Risk Management Report		•	
Failure Analysis	•		•
FMEA Form			•
Action Tracking, Newsletter			•
Optional: Questionnaire (Appendix C)		(•)	

Recommended Additions for your Comprehensive Development Process

Action and Project Management			•
Document Management for your Development Documents			•
Visual Process Development			•
Visual System Development			•
Process Consulting	•	•	•
Software and Method Trainings	•	•	•
Project Support	•	•	•

V+V: Design Verification and Design Validation

FMEA: Failure Mode and Effects Analysis

Optional: Can be supplied if required

PLATO e1ns – The Web-Based Product Innovation Platform



Web Capability

All product development data is accessible to every team member worldwide and across all locations.



Scalability

The system is growing in terms of technical requirements (e.g. number of product and process data) and a flexible number of users.



Collaboration – Communication

Model-based work guarantees that all team members have the same understanding of the system and that they are always up to date.



Lessons Learned

Approved standard templates ensure a uniform way of working and significantly reduce the effort.



Safety – Security – Compliance

Access to the system is only possible with the appropriate authorization. Any actions requiring a signature can only be enabled with password entry.