

INSPIRING PERFORMANCE

Making SOPs part of a process centric model – the journey

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Novartis Pharma Development – Bringing New Medicines to Market

Novartis aspires to transform drug development by applying innovative approaches to enhance quality and productivity of clinical development and significantly decrease development time.

Innovative products in five major therapeutic areas

- Cardiovascular & Metabolism
- Oncology
- Neuroscience and Ophthalmics
- Respiratory
- Integrated Hospital Care



Strong pipeline of new medicines to help drive future growth

Where we were 5 years ago - SOPs

- One dimensional i.e. text based documents, often complex and confusing (lengthy Word documents)
- Functional views and ownerships did not make inter-relationships clear
- Ensured compliance but scope overlaps, redundancies & gaps
- Detached from holistic views of the organization and its quality system
- Disconnected from Lean and continuous process improvement/operational excellence thinking

The Vision for Clinical SOPs / Industry Standards – June 2006

- Provide a ‘one-stop-shop’ access to ‘everything you need to do your work’
- Improve understanding of essential steps to be conducted in order to achieve compliance
- Relate SOPs to the overall Clinical Development Process
- Integrate Clinical quality modules, easy access to regulatory references,



Where We Are

- End to end process flow defined at high level, as a reference, with plugged-in process-mapped SOPs
- SOPs are process-mapped, reviewed and approved in process tool, then transferred into a document
- Further guidances and tools attached to and accessible from process-mapped SOPs
- Quality Manual, & regulatory references directly related to each SOP
- Read and Understand enabled electronically through the document management system

Our SOPs Today - Overview

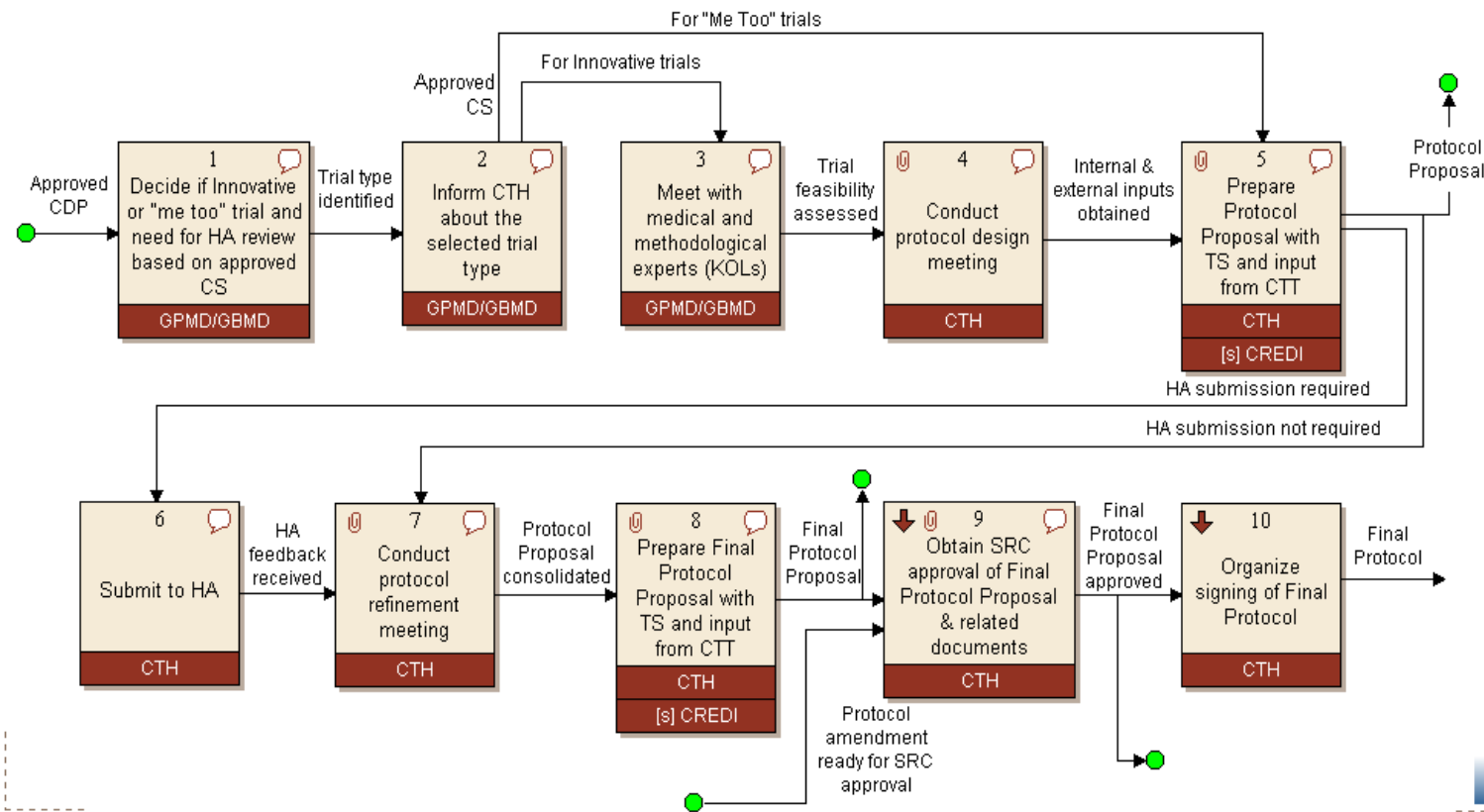
SOP-0015100 - Developing, Reviewing, Approving & Amending Protocols

Owner: Michele Mercuri
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 Version: 4.1



Purpose & Scope | Definitions | Roles & Responsibilities | Related Documents | Abbreviations | Related SOPs | Regulatory References | Related Quality Modules

BU Oncology Trials | ED Trials | Development of Amendments



But Still...

- Associates read (lengthy) text document, often off-line (paper)
- Document management system is the driving system (criticality, R&U, lifecycle....)
- High number of SOPs, even higher number of attached additional documents
- No formal or consistent training approach



Process ?

Training ?

Text ?

What we need has not changed

- Well documented procedures
- An integrated Quality System
- Concrete, actual training on SOPs and way of working
- A process flow that associates can use as a reference model,
- Make is such that :
 - ...Compliance is our standard way of working...
 - The vision is still the same

The Revised Quality Management System



Process

Compliance

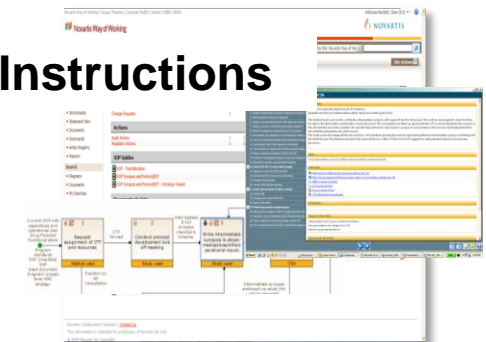


Navigation



One Stop Shop

Detailed Instructions



Read & Test

The Revised Quality System

One Stop Shop (revised!): The SOP is now part of a wider ‘package’ of multi-dimensional* process-focused content that gives each user what they need to perform their role or complete a task. This can be in the form of text, process diagrams, web links, pictures, templates, application links etc...

- End-to-end process perspective promoted and integrated into the Quality System (QS)
- Quality modules provide clear view of WHY
- Higher level SOPs emphasizing the WHAT, show the essential WHO’s and provide better flexibility for the HOW

* Quality Modules, SOPs, working processes, tools, training material, R&T.....

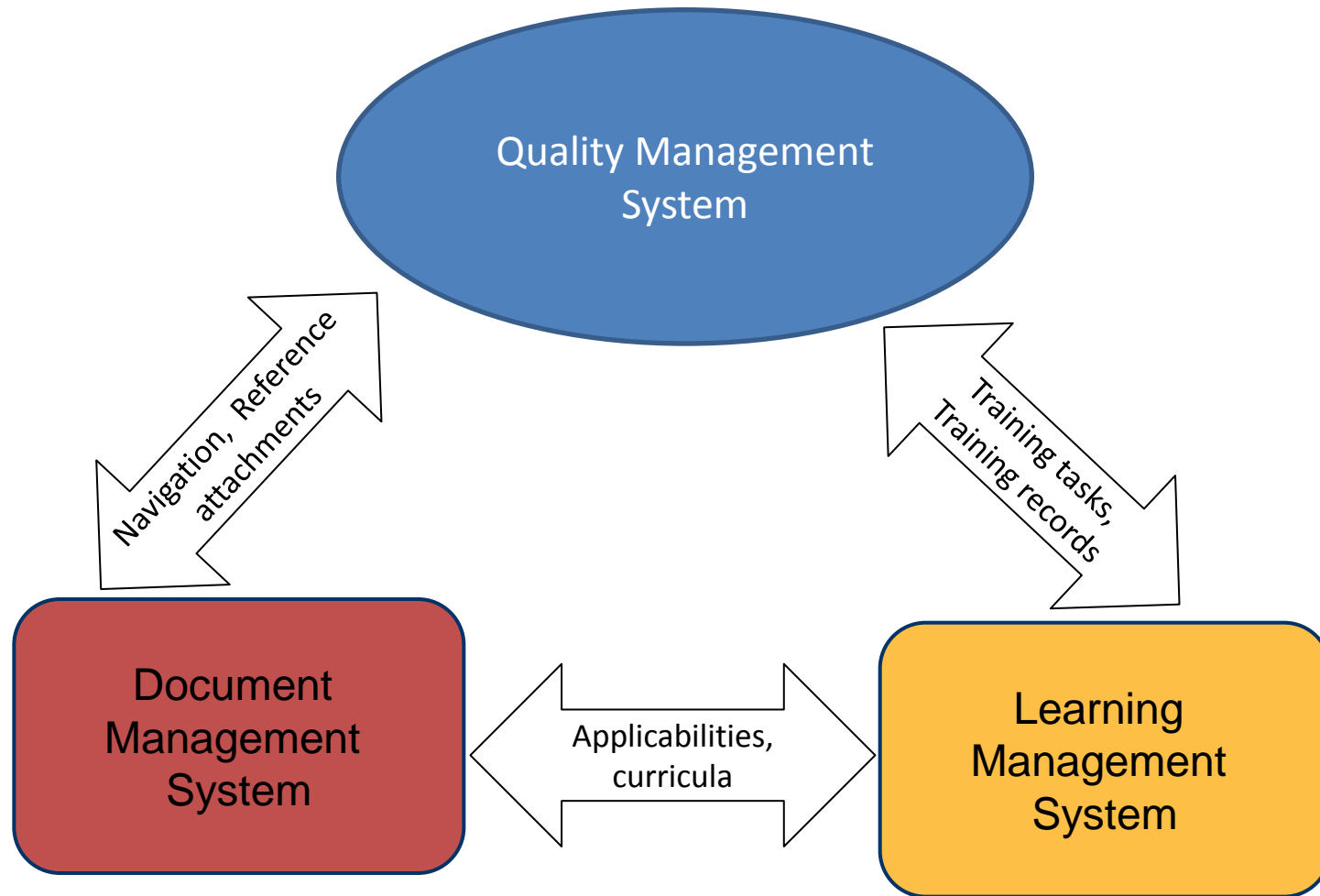
What are the challenges of a process-based approach to a Quality System?

- Shifting from document-centric thinking to holistic process-thinking view
- What type of content is in a document, what type of content is in a process ; Where are the why, what, who, where, when and how stored and managed
- How do you comply with and manage regulatory requirements & business controls
- How do you articulate the business view (detailed working level processes, subject to dynamic continuous improvement) with the regulatory view (essentials dictated by internal & external rules)

Key Enablers

- Start from the overall process to bring existing content in
- Essential mandatory steps highlighted and included in SOPs
- Guided navigation through the process model, with additional explanations, help end-users follow the process, understand key interfaces/deliverables between functions and roles
- Read & Test replace Read & Understand
- Web-based trainings with examples, prepared centrally
- Having the right architecture to deliver the functionalities

Main applications to be integrated



Technical challenges of a process-based approach to a Quality System

- We are not starting from a blank page
- Technical Integration of different systems (all being upgraded/changed at the same time)
- Integration into the LMS for R&T to complete the cycle of create-review-authorize-publish-confirm
- Validation of the entire system, including interfaces between applications
- Applying process governance

What influenced the application section?

- 21 CFR part11 compliance
- Ability to link regulatory requirements
- Good content governance e.g. versioning, scheduled reviews, approval workflow
- Personalized view on processes, documents, etc....

Next Steps

- Onboard users
- Ensure users are trained
- Roll-out
- Support change and transformation
- Comply with the new way of working
- Refine and develop further
- Track compliance
- Get the benefits!