

**Practical Experience with SOP-  
Based Task Tracking Automation  
for Pharma: A Case Study**

Drug Lifecycle Tracking Application (DLTA)  
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**Mukesh Kumar**      **Noopur Varshney**



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### SOPs Require Tracking for Compliance

- SOPs give us a list of steps in a process
- A complete process may require multiple SOPs
- Each SOP involves multiple personnel
- Each individual may need to follow 5-15 SOPs
- SOP compliance depends on tracking of tasks
- Untimely or incomplete SOP tracking is the most common audit finding
- **SOP Task Tracking can be automated**



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### Automation of Tracking Requires..

- Flow charts for each SOP mapping the processes covered, giving steps, roles, deliverables and time-lines
- Cross-Functional maps to connect the individual flow-charts
- A platform technology that use the cross-functional maps to automate task tracking



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### Advantages of Holistic Tracking

- Each task assigned to a "job role"
- Roles are customizable and can be linked to job titles, job responsibilities, and training
- Real time performance (quality and time) tracking for each team member
- Who's responsible for what gives people incredible recognition and accountability for their work



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### Dynamic Work-Flow Management

- Adds ability to work together dynamically
- Centralized transparent team communication
- Plan and execute at the same place leads to real-time fluid planning
- Real-time task tracking and accountability
- Reduces project management costs by time-saving on meetings and gets rid of painfully long email threads



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### Case Study: Large Organization

- Many users with different roles
- Multiple departments with different responsibilities
- Each department has their own set of processes that are defined in the form of SOPs
- Processes interconnect regardless of the department
- Regulatory deadlines that cannot be missed
- Lot of manual work and disconnected systems



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### Case Study: The Issues

- No single place to get all the information/data regarding the different deliverables
- No uniform way of tracking the progress of the deliverables review – who, when, what, etc.
- Work assignments were being distributed via email and then tracked manually either in Microsoft Project or Excel
- Data was distributed across various databases, legacy systems, and software that don't communicate with each other and weren't integrated
- Lack of interactive collaboration (team silos) between different departments and offices working on same deliverables



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**Case Study: The Issues**

- Unable to determine resource capacities and allocations leading to assigning reviewers that already have intense workloads
- Unable to track resource hours, costs, and expenses per project or per task
- Inefficiencies in processes because of disconnected systems and very tedious manual work
- Various manual reports used by different managers leading to data that needs to be manually put together before a holistic view can be attained with a chance of becoming stale since it's not real time

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**Case Study: The Solution**

- Move to System-Driven Processes
  - Systems create efficiencies by moving tasks through a standard operating procedure
- Automate Processes Where Possible
  - Automating processes can improve the quality and efficiency
  - Build a repeatable framework to enforce a standardized process
- Enable Real-time Measurement and Reporting
  - Single system for entering data, doing work and reporting

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**Initial Experience**

- Selling the idea of an integrated platform
- Used prior experience with an off-the-shelf product to show how processes can be automated
- Discussions with key stakeholders to create detailed flow charts of the SOPs as they existed, capturing the relationships and roles of individuals involved
- Prototype demos and constantly incorporating feedback to ensure comfort level

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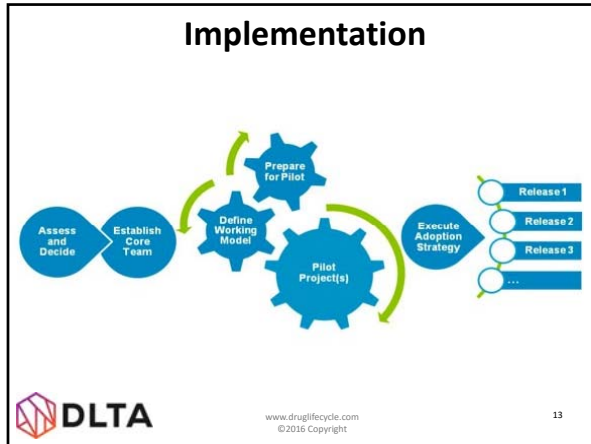
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### Implementation

- The implementation consisted of doing a pilot first with a core team and then did a mass rollout
- The pilot consisted of talking to stakeholders and ensuring their requirements were incorporated in DLTA, configuring it, doing prototype demonstrations, incorporating feedback and then going live
- Implementation consisted of templates for processes, roles for work assignments, reports and dashboards for viewing relevant information, required approval processes to enhance automation and keeping things in single system

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### Integration with Legacy Systems

- Existing legacy systems with lot of historical data
- Legacy systems still the point of entry
- Integration helped ensure the data is streamlined between two systems
- Helped during transition
- No disruption to work

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### Integration in the Organization

- Cloud-based product comes with a sandbox environment
- Prototypes were created and approved in sandbox
- Approved configurations were migrated to Production environment
- A core group was selected and given access to the production as part of the pilot



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### Key Issues and Solutions

- Change in the status quo - no one wants to change things
- A need to streamline things and increase the ability to be able to track progress and be able to report on key performance indicators
- Is it bringing too much transparency?
- What about our legacy data?



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### Training of Personnel

- Training was custom tailored: took the product training material and modified to reflect customer's processes, roles, configuration and report needs
- Multiple ways of training were created so that users could pick one that would work best for them: instructor-led, CBTs, 1-minute modules, training handouts and guides



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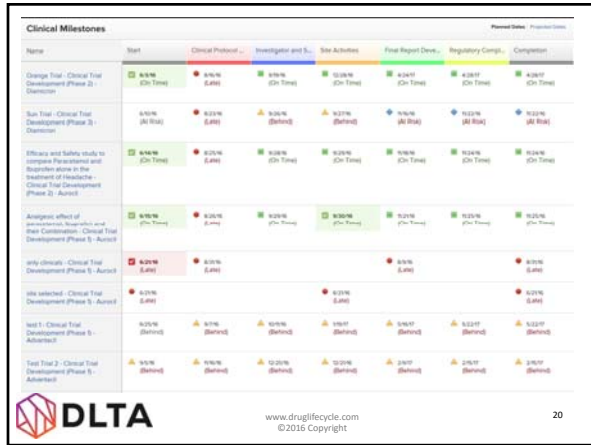
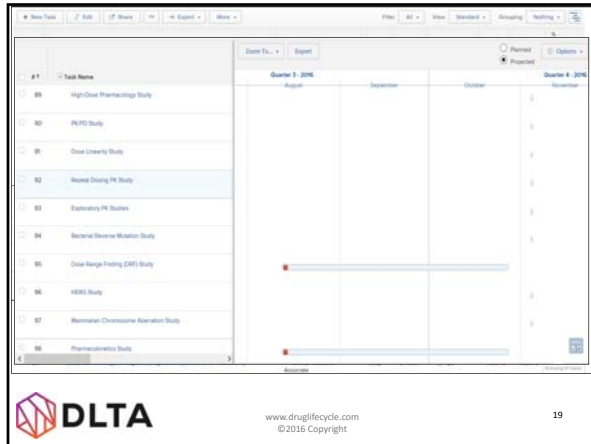
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### Support Needed

- Helpdesk support will be provided with DLTA consisting of a portal where users can submit their queries and will get responses based on the priority
- Support team will consist of certified individuals and responses will be in line with customer expectations
- Multi-tiered support can be provided on an as-needed basis



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### Key Benefits

1. Reduces guess work helping your team with completing and reporting work on time
2. Centralized platform for all work assignments with real time tracking from a high and granular view
3. Increased visibility, accountability, and collaboration
4. Eliminated 10+ hours a week spent in status meetings.
5. Reduced the project planning and the initiation phases by 5+ days
6. Meeting or exceeding the review timelines set by regulations



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### Thank You!

#### Questions and Comments

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