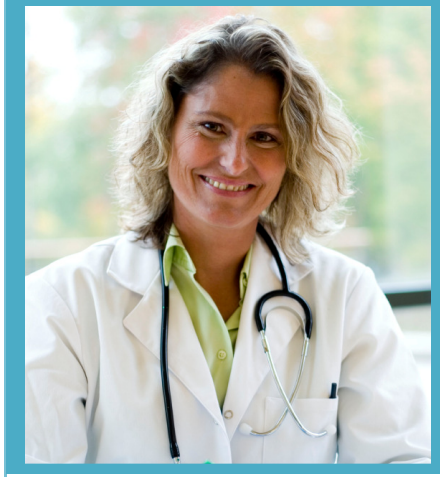
Danielle – Lab Analyst, Bioanalytical Testing, Life Sciences



"I have to have the right SoP open on my workbench."

- Age: 30 years
- Education: B.Sc. in Biochemistry and Bimolecular Biology
- Experience: 7 years experience with BioLabs
- Career goal: Clinical Laboratory Scientist
- Lifestyle: Single gal
- Interests:
- Attributes: Detailed, demanding, friendly

Goals

- Get her results approved by QA
- Avoid any deviations
- Read everything she needs to do her job
- Stay compliant

Needs

- Access to the project plan
- Quick and easy access to SOPs, Memos and deviations
- Better email management practices
- Easy access to templates, change request forms and all reference documents
- Access to equipment manuals
- Help managing the documents associated with a project
- A better way to get SOPs reviewed and approved

Tasks

- Running assays (experiments) and performing trending
- Creating and validating reports
- Changing reports to meet with acceptance criteria
- Documenting deviations
- Reviewing SOPs
- Helping to decide on which equipment to purchase
- Searching for SOPs, Memos
- Reading – SOPs, Memos, Reports, Project plans, study protocols

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Pain Points

- No visibility into project schedule
- QA – it's so hard to make them happy

Organizational Info

Reports to:

- Clinical Laboratory Scientist

Works with:

- Other Analysts
- Bioanalytical Research and Development team members
- Metrology – the group that calibrates the instruments
- Document Control – the group responsible for SOPs

Belongs to group:

- Bioanalytical Testing

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Background

Education
Danielle has a degree in Biochemistry and Bimolecular Biology from the state university. While she was at school she worked in a lab as a research assistant.

Her priorities are always changing: a sudden deadline might come up, or a new, urgent customer need could present an opportunity to the company. When this happens, she's pulled off the current project she's performing assays for and onto another one. Ramping up on the Standard Operation Procedures (SOPs) takes time, but the work is very much the same.

Danielle doesn't have much insight into the status of a project: the analysts at BioLab are only told what to work on, not why they're doing it. "It's like walking into a fog." Danielle receives an assignment to perform an assay and then she's given an amount of time to perform it.

Experimental Work
She works for the Bioanalytical Testing group and her role is to validate the test results. Every assay – or experiment – has an acceptance criteria. This acceptance criteria describes the controls, the standalones and the outliers. Danielle's job is to run the assay and compare it against the acceptance criteria. The information from the tests can be written, but more and more it's being captured by advanced equipment that outputs data to a database. These data sets are called data packets; QA compares the data packets with the acceptance criteria and if the data doesn't match the test doesn't pass validation. Their structured data is stored in a database in a relational way: all results from a particular sample are assigned to that sample; every result from an assay is assigned a Worklist ID. Danielle uses queries to generate reports.

Danielle meticulously maintains her laboratory notebooks. If she's not careful, she could have to repeat an entire series of experiments. She's also responsible for interpreting and communicating the results of an assay; she creates result reports that are shared with the various sites working on the same drug, with QA and with external groups.

She works on samples from preclinical and clinical trials. The samples from the clinical trials are collected by a Contract Research Organization (CRO). Part of her job is to work out data transfer plans between the CROs, Clinical Data Management and BioLabs. If the way the data is defined isn't done before the project begins, there's a lot of cleanup needed in order to do proper analysis.

Documents
She lives on email: that's how all communication is done within the Bioanalytical Testing group. Requests for information, reagent expiry notices, requests for reports and requests for samples are all sent to her. She gets email invites to meetings where her colleagues propose new, better ways of working together and where project status and timelines are reviewed with management.

She's also responsible for writing SOPs and reviewing others' SOPs. Once an SOP is finalized, it's reviewed by the Director and then scanned into LES. It's marked with its effective date – this is the date it will begin being used. "I have to have the SOP open, legally, on the bench every time I do an assay." A common type of SOP she deals with is the procedure for creating a reagent – a substance consumed during a chemical reaction. Danielle hates when SOPs are reviewed and changed: when an SOP changes, she has to change the way she works.

She also reads a lot of memos, which are like SOPs, just smaller. Managers write SOPs that include information about project timeline updates changes to testing procedures. They're electronically signed and then distributed to the Laboratory Operations team and Analysts.

Danielle is supposed to refer to the study protocol as she's doing her work but, "It's 100 pages - I haven't read it." The protocol describes the subjects, the assays and what to document. It's the principal document that the FDA sees: "It runs the whole show."

Study Design
She and her team work with the Study Director to design the studies they will perform to generate enough quantitative data about their drug candidate to submit an Investigational New Drug Application to the FDA. The studies they develop must be highly sensitive and involve reliable assay methodologies that allows for rapid and accurate analysis.

New Equipment
Danielle also participates in reviewing and requesting new equipment. BioLabs has a very standard set of operations for bringing in new equipment and updating the SOPs related to the equipment. She works with Validation (QA), Facilities and Metrology – the team responsible for calibration of equipment – to get the equipment requested, purchased, installed and will help write the SOP for how to use it. Log books are used to track the maintenance of the instruments. Danielle has to submit a request to the Document Controllers every time she wants to find an SOP. "It's cumbersome, but once you find your stuff it's ok."

Bioanalytical Testing Solution Tree Design

The following table shows the BAT solution tree design. See Appendix A for the designs shown during the review session.

Tree Node	Type of Node and Node contents
BAT Solution	Community – for BAT team members
My Email	Folder – for email
Tasks	Folder – contains the user's workflow tasks
Memos and SOPS	Folder – Repository for all SOPs and memos. An SOP is a Standard Operating Procedure and is a formal, step-by-step document that must be followed. A memo is a supplementary communication that is made in addition to an SOP.
All SOPs and Memos Find an SOP Find a Memo	Needs to allow searching and browsing of SOPs and Memos. "All SOPs and Memos" would allow faceted browse.
Deviations	Folder – Repository for all Deviations. Deviations are assays that have strange results. This is usually due to a scientist not following right procedure.
Search Deviations My Deviations Deviation Template	Allows Deviations to be searched for, contains a search folder that only returns the user's deviations and also has the Deviation template available.
Administration	Folder – Catchall for reference information
Templates	Templates by folder: Presentations, Memos, SOPs, etc.
Presentation Template Memo Template Sop Template Result Report Data Transfer Plan	These are documents that would exist in this folder. Presentations are given to stakeholders to report on progress of a particular project Result reports are final reports on the assays Data transfer plans are contracts between groups that describe how data will be formatted and shared
My Personnel Folder	Folder – Catchall for HR information
Training Certificates Performance Appraisals	These are documents that would exist in this folder.
Request Forms	Folder – Catchall for request forms
Change Request Request for Information Request for Proposal Vacation Request BAT vacation spreadsheet Work Order Inventory Request Archives Request	These are documents that would exist in this folder.

Reference Documents	Folder – Catchall for reference material
Generic SOPs Log Book Search Manuals	These are documents that would exist in this folder.
Equipment	Virtual hierarchy – Allows all equipment assets to be browsed.
By Name By Asset Number By Functional Category	Documents which could be show in this virtual hierarchy include: Master Service Agreement, Warranty, Manuals
My Projects	Subscriptions Folder – the BAT team works on one or two projects at a time
MOR_002	Solution Folders by Project ID Projects are named based on the trial and the drug name
MOR_001	
PAL_001	
Correspondence	Email Folder
Administration	Folder
Study Protocol Data Transfer Plan Meeting Minutes Project Status Reports Project Timeline	These are documents that would exist in this folder. A study protocol describes why the study is being done
Trending	Folder – contains trending reports
Study Results	Folder
Final Results	Folder - multiple reports, broken down by folder
Final Interim Results	Folder – contains reports by assay. These are results that are given to the stakeholders to report on the status of the project
Report on Worklist ID	Webpage – allows reporting on the worklist ID. Worklist IDs are tied to the assays that a scientist will conduct. These IDs are how they report on the information they've collected
Data Packets	Folder – contains scanned copies of the data packets. Data packets are huge amounts of information about a particular assay.
QA Reports	Folder - Work in progress area. QA checks the test results of the tab technicians to make sure they didn't deviate from the SOP.