Witness & Review Best Practice Guide





Why Establish a Witness and Review Process?

Speed Up Filings

Regulatory agencies may require compliant documentation from you as you pull together material for your filings. This will require that experimental data is reviewed.

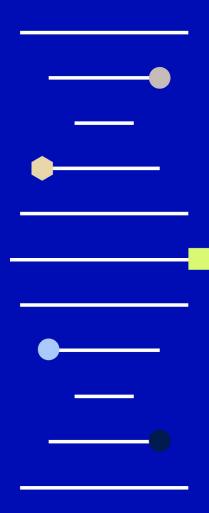
Promote Consistency

A consistent Review process ensures everyone has a clear understanding of what is expected of an entry, making it easier for people to submit experiments and notes for review.

Ensure Data Reliability

Data is more reliable when it goes through a review process.
Established guidance will ensure that data is input correctly, and reviews will ensure multiple eyes catch any mistakes.

Reviewing in Benchling



Setting up Witness and Review Processes

Let your team know what to expect

Build Enablement

Ensure your team knows your Witness and Review Process and can readily access that material

- 1. Develop SOPs for routine tasks.
- 2. Train your end users on the review processes you build.
- 3. Identify Super Users to capture and train different teams' needs.

Build Processes

Develop regular practices to protect data integrity

- Identify who is a designated reviewer for your organization.
- 2. Develop <u>checklists</u> alongside an SOP for a reviewer to understand what is necessary to complete their review.
- 3. Identify reviewer backups and define review turnaround times.

Project Settings

There are 2 options when setting up a new project – either use the default auditor review, or a custom-created review process

1. Auditor Review

Notebook authors select from a <u>pool of one</u> or more reviewers.

2. Review Processes

Set up multi-stage reviews. Set up options for sequential, parallel and self-reviews. Auditors can be selected from the Project or pre-defined Benchling Teams

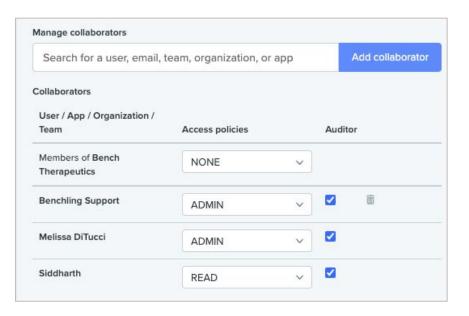




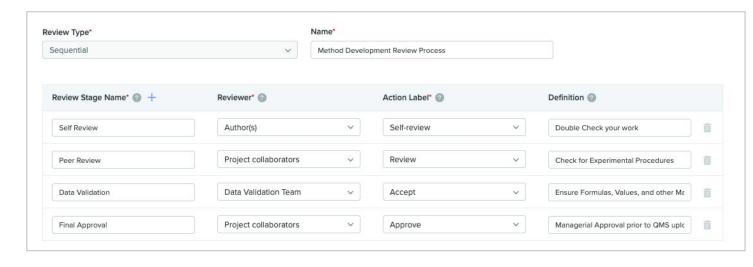


Review Options

Using the **Auditor Review** function, a pool of one or more reviewers can be assigned but only one person is required to complete an entry review.



Review Processes allow you to set up multi-stage reviews. Set up options for sequential, parallel and even self-reviews mean that multiple people can be assigned and required to complete an entry review.



For more on building Entry Review Processes, <u>click here!</u>

When should you send a notebook for review?

Create ideal turnaround times for experiments

Longer Experiments

Pros

 Long-running projects can be captured in one entry, with all results captured chronologically

Cons

Data is only reviewed at the end;
 unreviewed errors early in the process
 can cascade to later experiments

Examples

Long time-course studies, Method
 Development studies

Shorter Experiments (Best Practice)

Pros

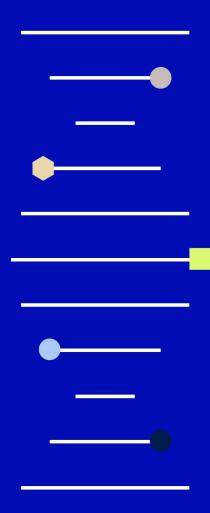
 Assays can be reviewed as they're completed, ensuring data for further experiments is accurate

Cons

- You have to create a compiled entry for larger projects (using @mentions or links)
- More reviews sent over time

Examples

 Routine Assays, or Experiments with many downstream dependencies



Decide what is required for a completed entry and review

Work with your team to make decisions regarding the Review process for your assays. This ensures everyone is enabled to help with document compliance. Be sure to document your process!



Entry Requirements (Examples)

- 1. What is expected for an entry to be complete?
- 2. How long should entries be?
- 3. What additional content should be attached to an entry?



Reviewer Requirements (Examples)

- 1. How many reviewers are needed?
- 2. Who should be a reviewer?
- 3. How much time should a review take?
- 4. What should a reviewer validate?



Create SOPs to document your decisions

- 1. Once decisions are made confirming the review process, document them in an SOP
 - In the case of an audit, a regulatory agency may request to see the rules your team used to create and review entries
- Identify whether you need to develop one Review SOP to cover all review requirements or a number of assay-specific review SOPs

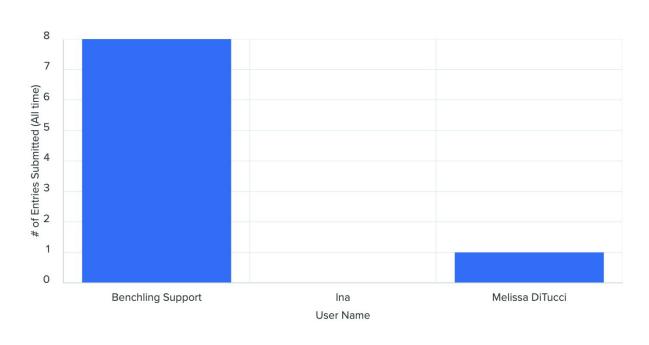
Enable Reviewers

- 1. Maintain all SOPs in a centralized location. Clearly communicate the location to scientists
- 2. **Develop <u>quick checklists</u>** alongside an SOP for a reviewer to understand what is necessary to complete their review
- Reviewers should be familiar with any assays performed to ensure that data is accurate, and experiment is conducted properly
- 4. **Be careful of bottlenecks!** Make sure that you have enough reviewers to match the throughput of that process

Best Practices for Witness and Review

Monitoring Notebook and Review Turnaround Times

Keep track of your team's reviews to ensure notebooks are reviewed in a timely manner



<u>Insights Dashboards</u> can be created to measure Turnaround Time at different review stages:

- How long has a notebook been open?
- How long has a notebook been waiting for review?
- How many entries are currently in review?

Create <u>Saved Searches</u> and <u>Share them with</u> <u>users</u> to track entries under review

Resources for Witness and Review



Sending entries for review



Reviewing entries and reassigning review stages



Create Review Criteria



Creating Review Processes