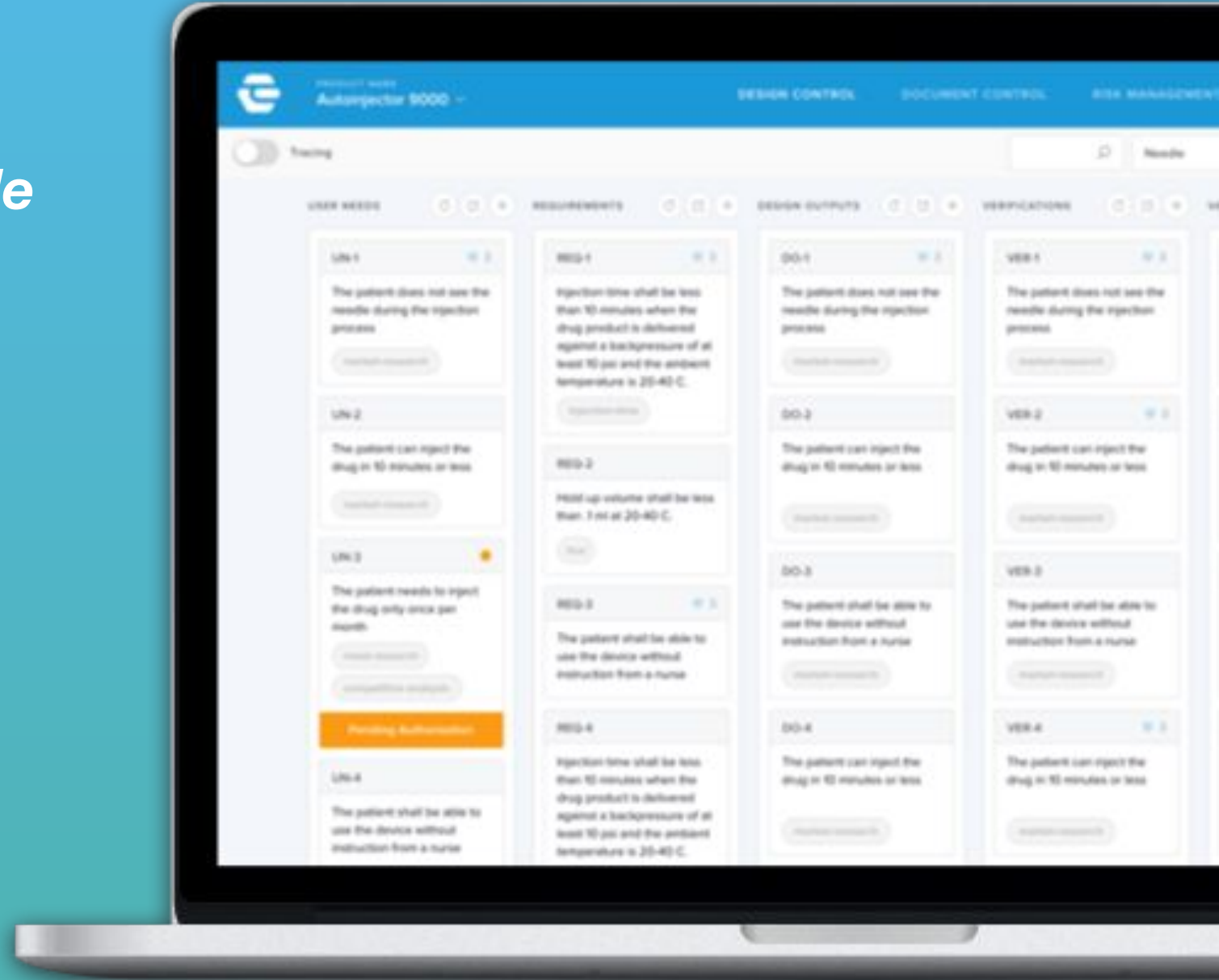




Succeed with Training Module for Admins



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Overview

- Regulations
- Overview of Training Module
- Training Module workflow
- Setting up Roles
- Company Training Status
- Audit Prep
- Best Practice Tips
- Resources

Regulations

Regulations such as ISO13485/ISO 9001/ FDA 820.40 outline guidelines for Training

FDA Guidelines

*Each manufacturer shall **establish procedures** for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities.*

*Training shall be **documented**.*

(1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.

(2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.

Overview of Training Module

- Easily assign & manage Curricula
 - Curricula can be composed of documents and/or task.
- Create Curricula based or manual one time training based needs.
 - Admins can assign training as recurring or one time training. Recurring training assignments will automatically be assigned with each revision updated.
- Managers can easily their team's training assignments and completion.
 - Managers can track their teams training assignments to ensure compliance.
- Filter & and Export training records for audits.

Training Module Workflow

Curriculum

| Ad-Hoc | Recurring |
|--|--|
| <ul style="list-style-type: none">● Assigned to roles● Documents (with quizzes) and tasks● One time training | <ul style="list-style-type: none">● Assigned to roles● Documents (with quizzes) and tasks● Reassigned with each document revision● Reassigned when task repeat date is achieved |
| <p><i>Example: Employee Onboarding</i></p> | <p><i>Example: Procedures, Work Instructions, Quality Manual</i></p> |

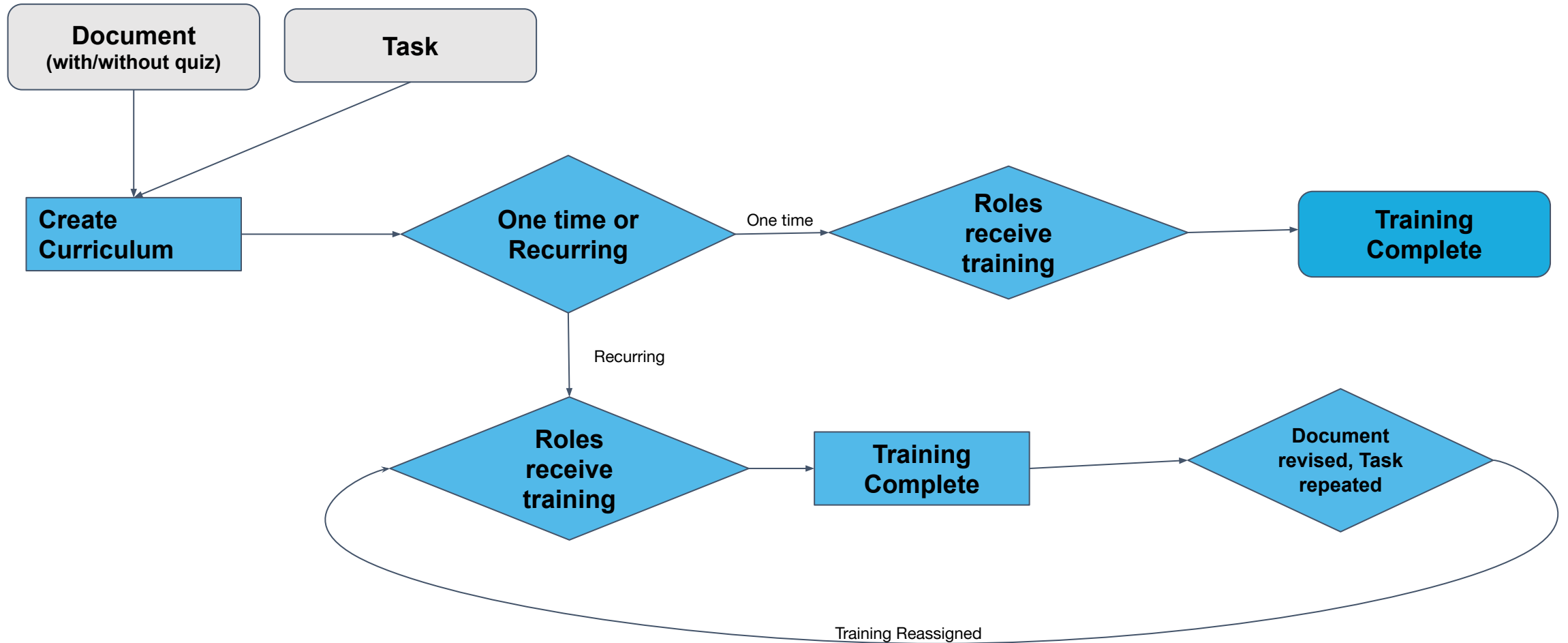
Manual Training

- Assigned to individual users
- Documents (with quizzes) or tasks
- One time training

*Example:
Attend a course/conference for career development*

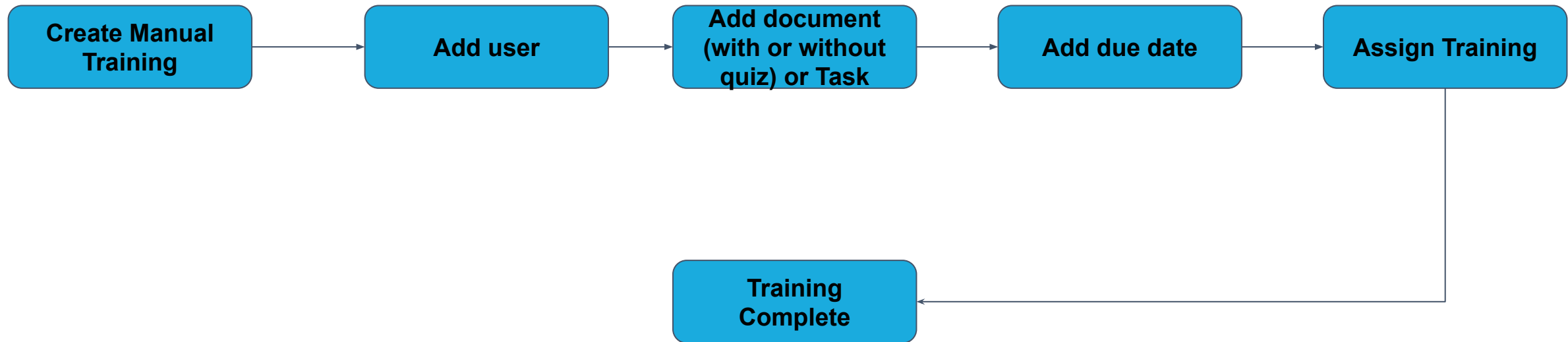
Training Module Workflow

Curriculum workflow



Training Module

Manual training workflow



Setting up Roles

Purpose of roles is to assign training by group function or responsibilities.

Examples

- Hardware only or software only product
Engineering, Quality, Management, Product, Clinical etc.
- Hardware + software product
Engineering- Hardware, Engineering-Software, Quality, Management, Product etc.
- Contractors/ Seasonal

Company Training Status

Training Matrix

Matrix View Table View

Filters Hide Inactive Users & Training Tasks

Export Clear

| | Miscellaneous123 Company Logo | QSM003 Quality System Manual Part 3 Quality Policy | QSM004 Quality System Manual 4 | QSM007 Quality System Manual | QSM123-1 QSM1 Quality System Manual Overview | QSM456 Quality System Manual Part 2 Glossary | SO |
|---------------|----------------------------------|---|-----------------------------------|---------------------------------|---|---|----|
| | Document | Document | Document | Document | Document | Document | |
| Jacob Graham | | Completed On 2019-03-18 | Due Date 2020-06-03 | Due Date 2020-10-09 | Due Date 2021-03-19 Previous 5 | Completed On 2019-03-18 | |
| | | COMPLETED | OVERDUE | OVERDUE | ASSIGNED | COMPLETED | |
| Manasi Shukla | Completed On 2020-01-30 | Completed On 2020-01-17 | Due Date 2020-06-03 | Due Date 2020-10-09 | Completed On 2020-04-09 Previous 8 | | |
| | COMPLETED | COMPLETED | OVERDUE | OVERDUE | COMPLETED | | 1 |

- Training Metrics
- Filters
(by status, document)
- Export Reports

Audit Prep

- Pull training record for a specific person
- Curricula per function
 - can export those reports
 - pull training record

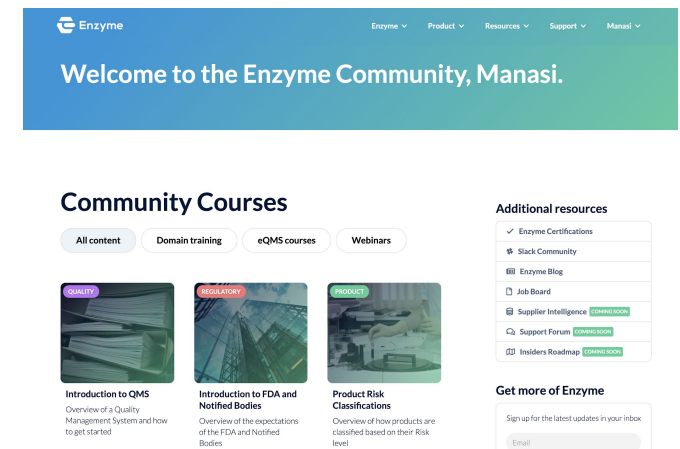
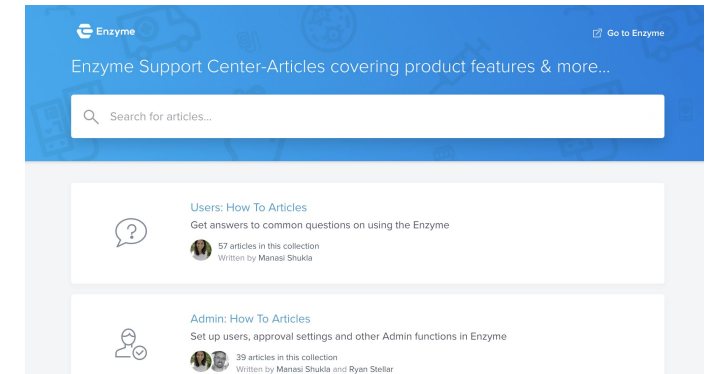
Best Practice Tips

- Focus on roles, recurring training, organize curricula based on functional needs
- Create an all employee role
 - Quality policy, quality manual, security related training documents, training SOP, Complaints Handling
 - Annual Training for all employees (task repeat = 365)
- Make sure training is *active*, keep it on
- Maintain training (or add new training) with the approval of new documents (a training question should be in the CRAQ)



Resources

- Support Center
 - Comprehensive knowledge base
 - Articles for every feature (most with videos)
 - In-app chat support
 - Live training
- Community
 - Detailed training courses (user & admin)
 - Courses on Life Science product development
 - User Slack Group
- Enzyme Consulting






Still interested in a pilot?

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