

## NTHRYS WORKSHOPS.

# Biocontrol Product Regulatory Dossier and Compliance Workshop

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## Core Regulatory Dossier Preparation Principles for Biocontrol Products

Understand the structure and purpose of regulatory dossiers for biocontrol products, including product identity, technical sections, safety information, and data organization.

[Dossier Structure](#) [Data Organization](#)

Review how efficacy evidence, quality information, biological characteristics, manufacturing details, and supporting documentation contribute to submission quality.

[Efficacy Evidence](#) [Quality Information](#)

Examine documentation logic for product composition, strain or

organism characterization, intended use, storage conditions, labeling content, and claims support.

**Product Characterization** **Claims Support**

Build awareness of risk-related sections addressing user safety, environmental considerations, handling precautions, and traceable supporting records.

**User Safety** **Environmental Considerations**

Understand how internal consistency, document control, data integrity, and clear formatting improve regulatory readability and review readiness.

**Document Control** **Review Readiness**

Strengthen planning for assembling defensible submission packages that align scientific evidence, product claims, and compliance documentation.

**Submission Packages** **Compliance Alignment**

**Overview**

**Biocontrol Regulation** **Documentation Training** **Compliance Quality**

## Workshop Overview and Learning Outcomes

Learn how to map scientific, technical, and regulatory evidence into organized dossier sections for biocontrol product submissions.

**Section Mapping** **Technical Evidence**

Understand how product specifications, efficacy documentation, manufacturing records, quality attributes, and labeling details fit into submission logic.

**Product Specifications** **Labeling Details**

Recognize the role of safety narratives, environmental considerations, traceable records, and consistency checks in regulatory review.

**Safety Narratives** | **Consistency Checks**

Develop awareness of document hierarchy, version control, completeness review, and internal cross-referencing for submission integrity.

**Version Control** | **Cross Referencing**

Build confidence in converting research outputs and product data into clear, regulator-facing dossier content with defensible structure.

**Research Outputs** | **Defensible Structure**

Gain practical understanding of how strong dossier preparation improves submission readiness, review efficiency, and biocontrol product positioning.

**Submission Readiness** | **Review Efficiency**

### **Agenda**

**Hands On Review** | **Three Day Format** | **Applied Learning**

### **Agenda Flow and Hands-on Components**

Day 1 introduces biocontrol product dossier architecture, regulatory content expectations, document hierarchy, and evidence grouping logic.

**Dossier Architecture** | **Evidence Grouping**

Day 1 also covers product identity sections, technical data summaries, claims support, labeling elements, and internal consistency expectations.

**Technical Summaries** | **Internal Consistency**

Day 2 focuses on efficacy sections, quality records, manufacturing information, biological characterization, and safety-related documentation planning.

**Manufacturing Information** **Safety Planning**

Day 3 integrates dossier assembly, review checklists, completeness checks, document control, and readiness evaluation for submission packages.

**Review Checklists** **Completeness Checks**

Hands-on components include section mapping, identifying evidence gaps, improving data flow, refining document order, and strengthening submission logic.

**Evidence Gaps** **Document Order**

Participants consolidate learning through practical review of dossier components, cross-reference quality, and regulator-facing clarity of biocontrol product submissions.

**Cross Reference Quality** **Submission Clarity**

### **Deliverables**

**Submission Guidance** **Awareness Outcomes** **Reference Support**

## **Deliverables, Support Material, and Frequently Asked Questions**

Participants receive guidance on dossier structuring, content mapping, evidence organization, submission logic, and documentation quality for biocontrol products.

**Content Mapping** **Evidence Organization**

Reference support emphasizes claims support, quality records, review checklists, document control, and regulator-facing presentation discipline.

**Claims Support** **Presentation Discipline**

The workshop is relevant to plant pathology researchers, biocontrol developers, regulatory teams, product managers, scholars, and technical staff.

**Biocontrol Developers** **Regulatory Teams**

FAQ topics address beginner suitability, dossier depth, evidence expectations, data organization, review readiness, and documentation completeness.

**Beginner Friendly** **Documentation Completeness**

Additional discussion clarifies how strong dossier preparation improves compliance positioning, submission efficiency, and product review confidence.

**Compliance Positioning** **Review Confidence**

Participants finish with stronger understanding of defensible regulatory dossier development for biocontrol product submissions and review preparation.

**Defensible Dossier** **Review Preparation**

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