

NTHRYS WORKSHOPS.

Regulatory Strategy for Plant Disease Solutions Workshop

[Workshop Index](#) [Duration: 5 Days](#)

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Core Regulatory Strategy Principles for Plant Disease Solutions

Understand how end to end regulatory strategy supports plant disease solution development from concept evaluation through documentation, review readiness, and market planning.

[Concept Evaluation](#) [Market Planning](#)

Review strategic pathways for product positioning, claims alignment, evidence planning, dossier sequencing, and compliance support across development stages.

[Product Positioning](#) [Claims Alignment](#)

Examine how efficacy evidence, safety narratives, quality records, risk sections, and labeling logic influence regulatory

acceptance and submission quality.

Safety Narratives **Labeling Logic**

Build awareness of how regulatory planning intersects with product development timelines, trial design, documentation control, and stakeholder communication.

Development Timelines **Stakeholder Communication**

Understand the importance of coordinated strategy for technical data planning, regulatory review preparedness, and long-term portfolio decisions in plant health products.

Technical Data **Portfolio Decisions**

Strengthen planning for plant pathology teams developing defensible and scalable regulatory approaches for disease management solutions.

Scalable Strategy **Defensible Approach**

Overview

Plant Pathology **Regulatory Training** **Submission Quality**

Workshop Overview and Learning Outcomes

Learn how to shape regulatory strategy across discovery, testing, validation, documentation, and submission preparation for plant disease solutions.

Submission Preparation **Validation Planning**

Understand how product claims, data packages, trial outputs, quality documentation, and safety considerations must align within a coherent strategy.

Data Packages **Safety Considerations**

Recognize the role of risk review, evidence mapping, regulatory sequencing, and documentation consistency in submission

success.

Evidence Mapping **Regulatory Sequencing**

Develop awareness of how product development decisions influence regulatory burden, dossier scope, review efficiency, and commercialization readiness.

Dossier Scope **Commercialization Readiness**

Build confidence in planning coordinated regulatory actions for disease management technologies, biocontrol solutions, and plant health interventions.

Coordinated Actions **Plant Health Interventions**

Gain practical understanding of how strategic regulatory planning improves compliance quality, resource efficiency, and long-term product positioning.

Resource Efficiency **Compliance Quality**

Agenda

Hands On Review **Five Day Format** **Applied Learning**

Agenda Flow and Hands-on Components

Day 1 introduces regulatory landscape awareness, product classification thinking, claim boundaries, and early strategy planning for plant disease solutions.

Product Classification **Claim Boundaries**

Day 2 covers evidence planning, trial outputs, safety documentation, quality records, and technical package development for regulatory pathways.

Trial Outputs **Technical Packages**

Day 3 focuses on dossier structure, section sequencing, risk summaries, labeling strategy, and internal consistency across

documentation sets.

Risk Summaries | **Section Sequencing**

Day 4 integrates review readiness, gap analysis, stakeholder communication, submission planning, and alignment of development and compliance milestones.

Gap Analysis | **Compliance Milestones**

Day 5 consolidates portfolio thinking, lifecycle considerations, response planning, and strategic review of end to end regulatory approaches.

Lifecycle Planning | **Portfolio Thinking**

Hands-on components include mapping strategy pathways, identifying evidence gaps, refining claims logic, and improving submission aligned documentation planning.

Evidence Gaps | **Claims Logic**

Deliverables

Strategy Guidance | **Awareness Outcomes** | **Reference Support**

Deliverables, Support Material, and Frequently Asked Questions

Participants receive guidance on regulatory pathway planning, evidence organization, dossier structure, risk section framing, and submission sequencing.

Pathway Planning | **Submission Sequencing**

Reference support emphasizes claims alignment, data package review, documentation consistency, portfolio planning, and commercialization aware strategy thinking.

Data Package Review | **Commercialization Strategy**

The workshop is relevant to plant pathology researchers,

regulatory teams, product developers, biocontrol innovators, scholars, and technical staff.

Product Developers **Regulatory Teams**

FAQ topics address beginner suitability, dossier depth, data planning expectations, claims scope, milestone alignment, and strategic review readiness.

Beginner Friendly **Milestone Alignment**

Additional discussion clarifies how strong end to end regulatory strategy improves submission confidence, product focus, and long-term planning quality.

Submission Confidence **Planning Quality**

Participants finish with stronger understanding of coordinated regulatory strategy for plant disease solutions from evidence generation to submission readiness.

Coordinated Strategy **Evidence Generation**

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