Advanced Solid-State Chemistry for Drug Substances Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

Advanced Solid-State Chemistry for Drug Substances is arguably the most critical discipline at the interface of pharmaceutical R&D and commercial manufacturing. The solid form of an Active Pharmaceutical Ingredient (API) including its polymorphs, salts, co-crystals, and amorphous forms fundamentally dictates its physicochemical properties. These properties directly impact drug performance metrics such as solubility, dissolution rate, stability, and critically, bioavailability. A lack of deep understanding in this area is the root cause of many multi-million-dollar development failures and regulatory setbacks. Advanced Solid-State Chemistry for Drug Substances Training Course is meticulously designed to bridge the knowledge gap, empowering scientists to master solid form selection, implement robust crystallization process development, and ensure product quality from early discovery to final drug product.

This intensive training goes beyond foundational theory, focusing on the practical application of cutting-edge analytical techniques and risk-mitigation strategies. Participants will gain hands-on expertise in X-ray Powder Diffraction (XRPD), Differential Scanning Calorimetry (DSC), Dynamic Vapor Sorption (DVS), and Solid-State NMR for comprehensive solid form characterization. The curriculum strongly emphasizes Quality by Design (QbD) principles for developing scalable, reproducible processes and managing the complex landscape of intellectual property (IP) related to polymorphism. By integrating real-world case studies and process analytical technology (PAT), the course provides the tools necessary to accelerate drug development timelines, strengthen IP portfolios, minimize batch variability, and confidently navigate demanding regulatory compliance pathways, securing a competitive advantage in the global pharmaceutical market.

Programme Curriculum

Advanced Solid-State Chemistry for Drug Substances Training Course

Introduction

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Course Duration

10 days

Course Objectives

1. Master the principles of Polymorphism, Solvates, and Hydrates and their impact on API performance.
2. Conduct strategic Solid Form Screening and Selection for optimal developability assessment.
3. Design and optimize robust, scalable Crystallization Processes using Quality by Design
4. Apply Process Analytical Technology (PAT) for real-time monitoring and control of solid-state attributes.
5. Interpret advanced data from XRPD and Single-Crystal X-ray Diffraction for definitive crystal structure determination.
6. Characterize and stabilize Amorphous Solid Dispersions to enhance solubility and bioavailability.
7. Utilize Pharmaceutical Co-crystals and Salts as crystal engineering strategies for property modulation.
8. Evaluate API Stability and Solid-State Degradation Kinetics using DSC, TGA, and DVS.
9. Relate Particle Size Distribution (PSD) and Crystal Morphology to final drug product processability and dissolution.
10. Formulate comprehensive Solid-State IP Strategies to secure patent protection against competitive polymorph claims.
11. Prepare robust Regulatory Submissions demonstrating solid form control and consistency.
12. Employ High-Throughput Experimentation (HTE) for rapid and systematic solid form discovery.
13. Troubleshoot common Manufacturing Failures linked to unwanted Polymorphic Transitions and Amorphization.

Target Audience

1. R&D Scientists in API and Drug Product Development.
2. Solid-State Chemists and Material Scientists in Pharma/Biotech.
3. Process Development Engineers.
4. Analytical Chemists and QC/QA Staff.
5. Intellectual Property (IP) Attorneys and Paralegals.
6. Formulation Scientists and Pre-Formulation Specialists.
7. Regulatory Affairs Professionals dealing with Chemistry, Manufacturing, and Controls sections.
8. Academic Researchers and Post-Docs transitioning to industry roles.

Course Modules

Module 1: Fundamentals of Pharmaceutical Solid Forms

- Introduction to crystalline and amorphous states and their impact on API performance.
- Understanding Polymorphism, the thermodynamic and kinetic drivers of form interconversion.
- Classification of solid forms.
- Defining Critical Quality Attributes related to solid form for regulatory compliance.
- Case Study: The infamous Ritonavir polymorphism crisis and its catastrophic supply chain impact.

Module 2: Phase Diagram Construction and Thermodynamics

- Theory and application of Phase Diagrams for multi-component systems.
- Determining the Thermodynamically Stable Form and understanding Enantiotropic/Monotropic systems.
- Calculating and interpreting Solubility and Dissolution advantages of different solid forms.
- Predicting Polymorphic Transitions under various process and storage conditions.
- Case Study: Using phase diagrams to select the optimal salt and form for a poorly soluble NCE

Module 3: Advanced Solid Form Screening Strategies

- Design of efficient Solid Form Screening campaigns
- Implementation of High-Throughput Experimentation (HTE) and miniaturized screening techniques.
- Salt Selection Strategy.
- Supramolecular synthesis, hydrogen bonding prediction, and co-former selection.
- Case Study: A successful co-crystal strategy that rescued a low-bioavailability API, leading to a new IP space.

Module 4: X-ray Powder Diffraction (XRPD) Mastery

- Advanced operation and maintenance of XRPD instruments and sample preparation methods.
- Peak indexing, qualitative phase identification, and quantitative analysis of polymorphic mixtures.
- Using Rietveld Refinement for advanced structural analysis from powder data.
- Understanding the effects of preferred orientation and crystallinity changes.
- Case Study: Utilizing XRPD for quantitative analysis of an unknown amorphous/crystalline blend during a manufacturing excursion.

Module 5: Thermal and Gravimetric Analysis

- In-depth interpretation of Differential Scanning Calorimetry thermograms
- Thermogravimetric Analysis.
- Determining Crystallinity and Glass Transition Temperature of amorphous materials.
- DSC-TGA and Hot-Stage Microscopy (HSM) for mechanistic insight.

- Case Study: Analyzing a drug substance's DSC/TGA data to identify a hidden hemi-hydrate form and its stability boundary.

Module 6: Spectroscopic Characterization

- Theory and application of Solid-State Nuclear Magnetic Resonance for molecular packing and structural confirmation.
- Using Raman and FTIR Spectroscopy for rapid in-line/at-line identification and polymorphic purity checks.
- Chemometric and multivariate analysis of spectroscopic data for process monitoring.
- Vibrational spectroscopy for identifying specific functional groups and intermolecular interactions
- Case Study: Using Raman Spectroscopy in a PAT application to monitor a slurry conversion from Form A to Form B in real-time.

Module 7: Crystal Structure Determination (SCXRD) and Databases

- Principles of Single-Crystal X-ray Diffraction and crystal growth strategies.
- Interpreting Crystal Packing and Intermolecular Forces
- Utilizing Cambridge Structural Database (CSD) and other resources for solid-state information mining.
- Understanding Disorder and its representation in crystal structure data.
- Case Study: Analyzing a published SCXRD structure to identify a critical short contact that explains poor tabletability.

Module 8: Amorphous Solid Dispersions (ASDs) and Solubility Enhancement

- The science of the Amorphous State.
- Design and preparation of ASDs using various polymers.
- Predicting and measuring Physical Stability and Recrystallization Kinetics of ASDs.
- Supersaturation generation and maintenance to maximize oral bioavailability.
- Case Study: Optimization of an Hot-Melt Extrusion process to achieve maximum drug loading without phase separation in an ASD.

Module 9: Crystal Engineering and Property Modulation

- Advanced concepts in Co-crystal and Salt design for targeted property modification.
- Modulating Hygroscopicity and Chemical Stability through solid form change.
- Tuning Mechanical Properties via crystal engineering.
- Strategies for generating Multi-Component Pharmaceutical Materials.
- Case Study: Engineering a co-crystal with superior non-hygroscopic properties to replace a challenging hydrated form.

Module 10: Crystallization Process Development and Scale-Up

- Fundamentals of Nucleation and Crystal Growth Kinetics and their control.
- Designing anti-solvent, cooling, and evaporative crystallization protocols.
- Controlling Particle Size Distribution (PSD) and Crystal Morphology (Habit) using process parameters.
- Addressing Impurities and their effect on crystallization
- Case Study: A scale-up challenge where secondary nucleation caused a massive shift in PSD, necessitating a change to a seeding strategy.

Module 11: Process Analytical Technology (PAT) and Control

- Integrating PAT tools into crystallization and drying steps.
- Developing Control Strategies and Design Space based on QbD principles.
- Real-time monitoring of Polymorphic Purity and Supersaturation.
- Validation and regulatory expectations for PAT implementation in a GMP environment.
- Case Study: Implementation of an FBRM probe and Raman for automated control of cooling rate to maintain PSD and polymorphic form.

Module 12: Particle and Surface Characterization

- Measurement of PSD using Laser Diffraction and Image Analysis.
- Analysis of Crystal Morphology and its critical link to filterability and flowability.
- Understanding Surface Energy and its role in dissolution and powder cohesion.
- Techniques like BET Surface Area and Dynamic Vapor Sorption
- Case Study: Correlation between PSD and final tablet dissolution failure, leading to a milling process adjustment.

Module 13: Solid-State Stability and Degradation

- Solid-State Kinetics of chemical degradation.
- Forced degradation studies and their role in understanding inherent molecular stability.
- Predicting and managing Polymorphic Interconversion during storage and formulation.
- ICH Stability Testing Guidelines and the role of solid form in setting shelf-life.
- Case Study: An unexpected Amorphous to Crystalline Transition in a finished tablet during long-term stability testing, traced back to moisture ingress.

Module 14: Regulatory and Intellectual Property Strategy

- Current ICH Guidance and global regulatory expectations for solid form control.
- Developing a comprehensive IP Strategy covering polymorphs, salts, and co-crystals.
- Addressing Patent Challenges and defending Solid Form IP in litigation.
- The content of a robust CMC Section for demonstrating solid form understanding.
- Case Study: A Patent Infringement case centred on the specific crystalline form of a blockbuster drug.

Module 15: Formulation and Solid-State Impact

- Impact of solid form on excipient compatibility and pre-formulation testing.
- Addressing Solid-State Drug-Excipient Interactions
- The role of solid form in final Dosage Form Performance
- Troubleshooting common manufacturing issues: capping, sticking, content uniformity.
- Case Study: A case of salt disproportionation in a finished tablet due to acidic excipients, causing dissolution failure.

Training Methodology

The course adopts an intensive, Blended Learning approach combining theoretical mastery with practical, Real-World Application:

1. Expert-Led Lectures.
2. Interactive Workshops
3. Real-World Case Studies
4. Problem-Based Learning
5. Virtual Lab Simulations

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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