



# Inhaled Product Development

With more than 30 years' experience, Quotient is a leader in the development, manufacture and assessment of inhalation products, helping clients to accelerate molecules from first-in-human through to proof-of-concept. Our integrated capabilities and vast knowledge encompasses pre-formulation sciences, formulation development, device evaluation, clinical trial manufacturing and the clinical assessment of a variety of inhaled formats for nasal and pulmonary delivery.

## Candidate Selection / Pre-formulation

- Development of Target Product Profile
- Salt/crystalline form discovery support
- Physical properties testing of drug substance
- Selection of the physical/salt form
- Inhalation particle design and engineering technologies
- Climate control chamber

## Formulation and Product Development

- Particle engineering (e.g. micronization or spray drying)
- Development of Dry Powder Inhalers (DPIs)
- Analytical characterization of aerosol formulations
- ICH stability testing of drug products

## Clinical Trial Manufacture

- Phase I and Phase II clinical trial manufacturing
- Analytical/QA/QP release of GMP clinical products
- Real-time adaptive GMP manufacturing
- Supply and global distribution for patient trials

## Clinical Pharmacology Assessment

- First-in-human studies
- Formulation/system optimization
- Device bridging
- Scintigraphic deposition studies
- Pilot and pivotal bioequivalence studies
- Biomarker and pharmacodynamic assessments

# Inhaled Product Development – Equipment

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## Spray Drying for Inhalation

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- ProCepT spray dryer
  - GEA Niro Mobile Minor spray dryer
  - SPX Anhydro MicroSpray MS-35 dryer
  - Aqueous and solvent
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## Processing Equipment

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- Low and high shear blending
    - Turbula, Bin and V-Blenders
    - TRV and PMA mixing systems
  - Particle size reduction
    - MC-ONE micronizer
    - MC-TWO micronizer
    - Sturtevant 2" micronizer
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## Encapsulation of Inhaled Products

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- Xcelodose 600
  - Quantos
  - Harro Hofliger Modu-C LS Drum filler
  - Small volume blister packaging
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## Aerosol Characterization Equipment

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- Anderson Cascade Impactor (ACI)
  - Next Generation Impactor (NGI)
  - Dose Uniformity Sampling Apparatus (DUSA)
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