



# IDD-Xpert in Numbers

## At the Core of pMDIs Pharmaceutical Development

IDD-Xpert International Drug Development Xpert  
453 rue de l'Industrie, Evreux, FRANCE

Preclinical phase/ Development phase

European & US Projects

Clinical phase

### Drug Substance

**Choice of supplier**

- Drug Master Files (DMF) Review
  - 9 DMFs (2015)
- Supplier Audits
  - 3 Audits (2015)
- Physicochemical Quality of API
  - Impurities, Assay, Particle Size Distribution, Infrared Spectroscopy

**Physico-Chemical Characterization**

- Polymorphism
- Hygroscopy

### Drug Product

**Preformulation/ Formulation**

- 1. Excipient**
  - Choice of excipient(s)
  - Choice of supplier(s)
  - 3 Audits (2015)
- 2. Formulation**
  - Definition (1, 2 or 3 APIs with 1 or more excipients, e.g. Oleic acid/Ethanol, HFA134a or HFA227ea)
  - Optimization at several scales
  - DoE
  - 2 DoEs (2015)
- 3. Process Transfer**
  - Scale Up to 100L
  - Failure Mode Effect Analysis (FMEA)
  - Process Transfer
  - 2 FMEA (2015)
  - 1 transfer (2015)

**Micromat**

**2L vessel**: 70 batches in 2015

**20L vessel**: 10 batches in 2015

**100L vessel**: 5 batches in 2015

**Submissions**

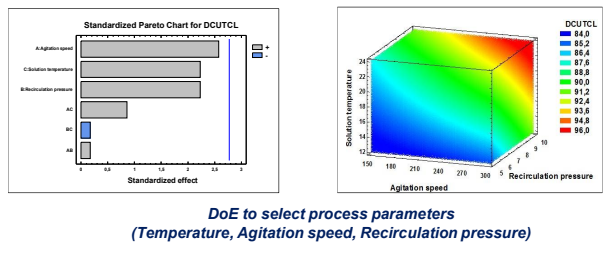
Europe (ANSM, MHRA...)  
US

IMPD, IND

Release of 17 clinical batches in 2015

**Pharmaceutical Development in accordance with Guidelines (FDA, CPMP)**

- Priming/ Repriming
- Temperature Cycling
- Canister Exhaustion
- Drop test
- Low Temperature Performance
- Effect of Resting Time
- Simulated Use Test



MAA, NDA, AMAA, ANDA

Stability testing of 6 registration batches in 2015

Variations Type I, Type II sNDA, CBE, PAS

Testing of 3 variations batches in 2015

### Control of Drug Product (HPLC, DAD, UV, Fluorimeter, GC-FID, IR, ACI, DCU, Spray Pattern, Plume Geometry,...)

**Method Development (Dry Lab Software)**: 22 in 2015

**Method validation**: 20 in 2015

**Robustness DoE**



**Container Closure System**

- Choice & Optimization (Valve, Can, Actuator, Spacer,...)
- DMF Review
- Extractables & Leachables
- Components Release

**Stability studies**

- Long-term: 25°C/60%RH
- Accelerated: 40°C/ 75%RH
- Intermediate: 30°C/ 65%RH
- 156 Stability Studies (2015)