Extractables & Leachables Studies

Custom programs for multiple modalities that conform to the latest regulatory guidelines

Center of Excellence for E&L Studies

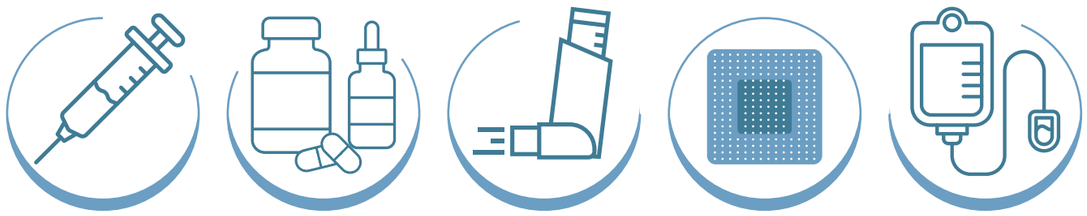
Risk-Based Study Design

Full Range of Instrumentation & Know-How

solvias

E&L Studies are
Not One-Size-Fits-All

Solvias offers E&L programs for multiple modalities that conform to the latest regulatory guidelines



Parenteral Products | Oral Delivery | Orally Inhaled & Nasal Drug Products | Topical & Transdermal | Single-Use Systems

E&L data are a mandatory part of the submission package for regulatory approval

- Our team has extensive experience working with the **FDA and EMA regulatory agencies**
- **USP and BPOG guidance** are followed and well understood
- Our team are active participants in **E&L focused industry working groups: BPOG and BPSA**
- **No CRLs issued** on over 20 years of designed work

A Solution for Every Risk

Experienced Subject Matter Experts
Program and regulatory strategy tailored to your needs

Direct Access to Our Scientists
Expert guidance throughout the program

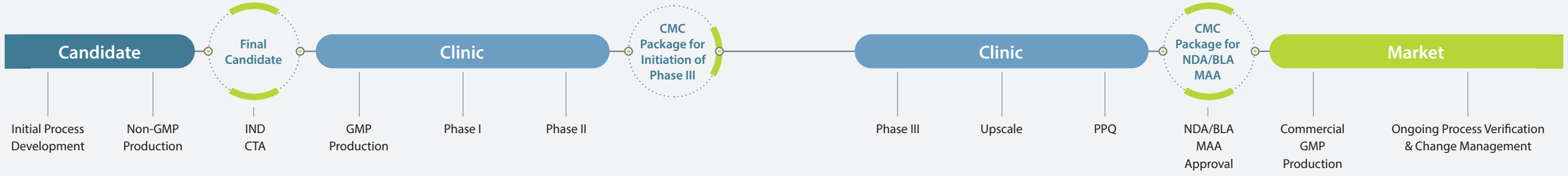
Dedicated Project Managers for Each Study
Proactive, transparent communication

Over 20 Years of Experience
Hundreds of successful programs have been delivered

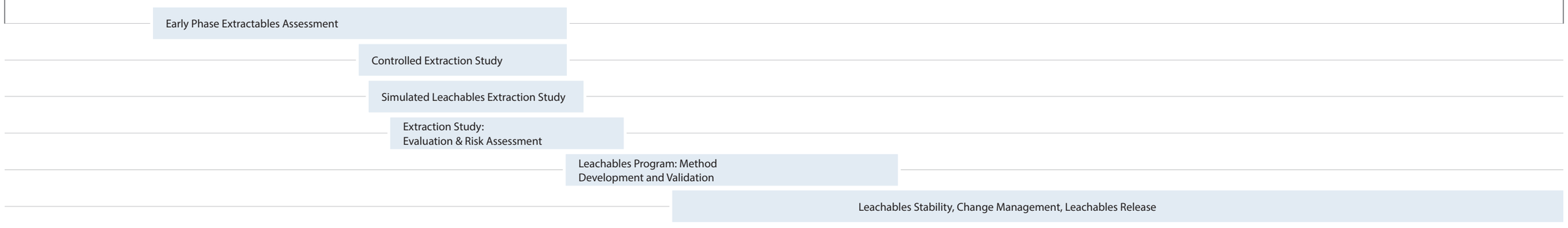
Solivas' E&L Studies have supported registration and commercialization of many well-known products

Partial list: Biosimilar production process systems, Vaccine production process systems, Fluticasone propionate, Salmeterol / Albuterol, Sumatriptan, Formoterol fumarate, Budesonide, Mometasone furoate, Triamcinolone acetonide, Azelastine HCl, Ethinyl estradiol, Morphine sulfate, Insulin, Bupivacaine, Naloxone

Product Development Process



Extractables & Leachables Program



Equipment & Infrastructure

Solvias has invested in the latest LC/GC-MS technology including HRAM instruments to allow reliable identification and quantification of E&L, ensuring successful regulatory outcomes

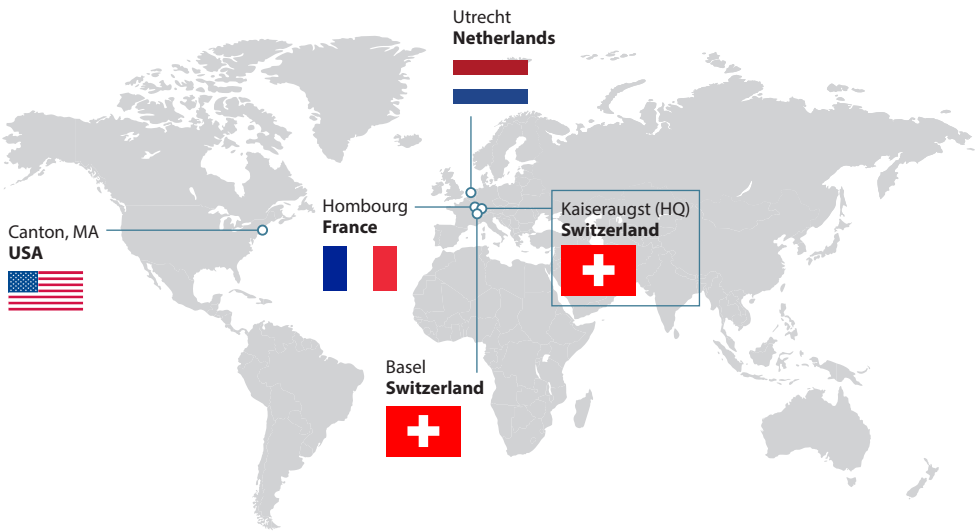
- GC/MS & GC/MS/MS
- Headspace GC/NPD & GC/FID & GC/MS
- UPLC/DAD/MS & UPLC/MS/MS
- UPLC-HRAM (Orbitrap/Q-TOF)
- GC-HRAM & Headspace
- GC-HRAM (Orbitrap)
- Full stability storage
- Total Organic Carbon (TOC)
- Microwave extraction oven
- Reflux Apparatus
- Soxhlet Apparatus
- Autoclave
- Orbital Rotation Incubators
- High Speed Mill
- Hydraulic Press

Solvias: Canton, MA Facility

- 30 minutes SW of Boston, MA
- Formerly Chemic Laboratories, LLC
- Track record and long-standing reputation as a center of excellence for extractables & leachables studies
- 22,500 sq.ft. facility
- 50 employees
- 9 FDA inspections (most recent Dec'22 – no findings)
- Controlled substance license for schedules 1–5
- Multiple DEA inspections
- Host ~ 20 client audits annually

Solvias Group

- CRO/CDMO
- Founded in 1999
- 800+ employees
- 5 Locations worldwide



480 Neponset St, Canton, MA, USA

1-781-821-5600

inquiries@solvias.com

solvias.com