



Extractables & Leachables Studies

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



Risk-Based Study Design

Full Range of Instrumentation and Know-How

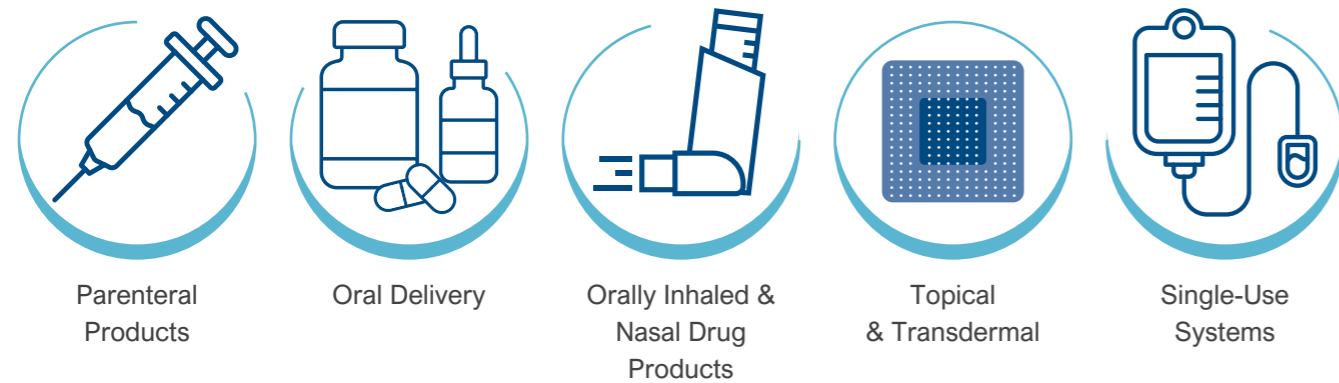
Structure Elucidation Experts and Proprietary E&L Database

Direct Access to Our Scientists

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



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**
- Our team are active participants in **E&L focused industry working groups: BPOG and BPSA**
- Extensive experience with **USP & BPOG**
- **No CRLs issued** on over 20 years of designed work

Reduce your risk with custom solutions

Justifying the right E&L study design is challenging. We can help you navigate this complex process.

- **Expectations can and do change** with each agency reviewer
- The expected level of **scientific rigor and technological capability** has evolved and is becoming increasingly challenging
- **Standard E&L packages are not product specific** and may not meet regulatory requirements

Expertise	Risk based approach: Study design requires expertise and careful cost benefit analysis. With years of experience and extensive regulatory knowledge, we avoid common pitfalls and successfully manage highly complex studies using both simulated and custom design.
Technology	Our structural elucidation experts have decades of experience in high resolution mass spec and can help identify unknowns not found in the data bases resulting in a 99% extractables identification success rate
Database	In addition to the publicly available data bases, Solvias has compiled an extensive, propriety, E&L-specific data base with over 6,000 compounds

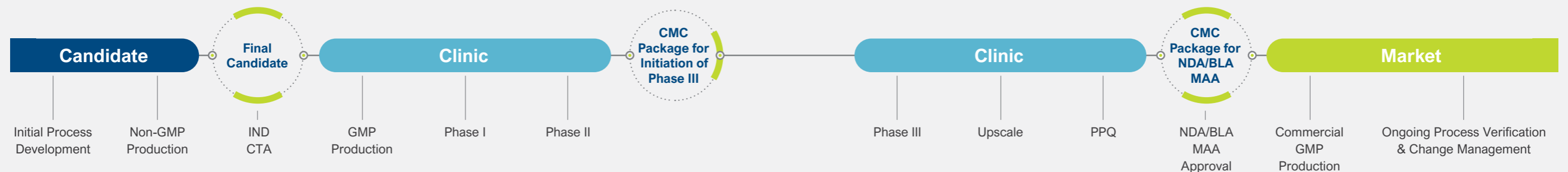
100s of Successful Programs Delivered

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

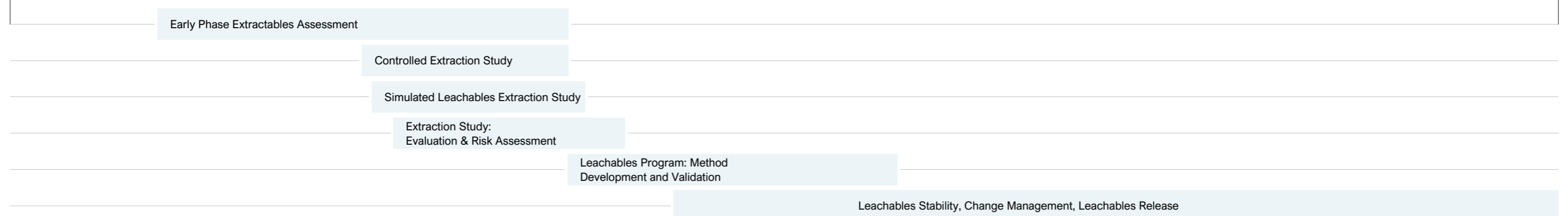
Partial list:

- Biosimilar production process systems
- Vaccine production process systems
- Closed System Transfer Devices (CSTDs)
- 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

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

Canton, MA

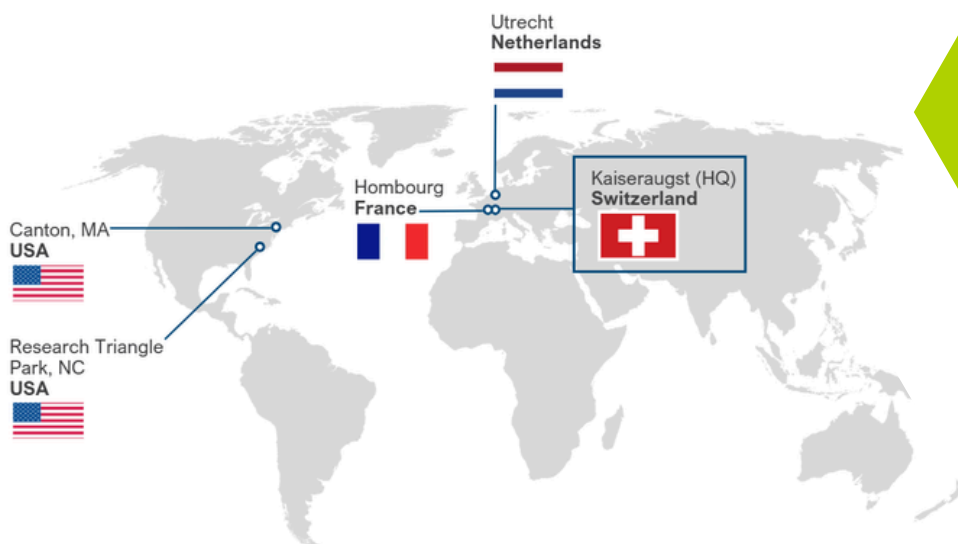
- Formerly Chemic Laboratories, LLC
- 30 minutes SW of Boston
- >2,000m² facility
- 9 FDA inspections (most recent Dec '22)
- Host ~20 client audits annually
- Controlled substance license for schedules 1–5
- Multiple DEA inspections

Kaiseraugst, CH

- 30 minutes SE of Basel
- >12,500m² facility
- Inspected by FDA (most recent Sep '23) and Swissmedic
- Host >100 client audits annually
- Comprehensive analytical services hub for small and large molecules
- Facilities and infrastructure for scheduled and highly potent substances

Why partner with us

- CRO
- Founded in 1999
- 800+ team members
- 175+ PhD-level scientists
- GMP, GLP, ISO9001 certified
- 23K m² of lab capacity
- 700+ customers worldwide
- 5 centers of excellence



Contact us to speak with an expert: info@solvias.com

  [solvias.com](https://www.solvias.com)

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