Extractables & Leachables Studies

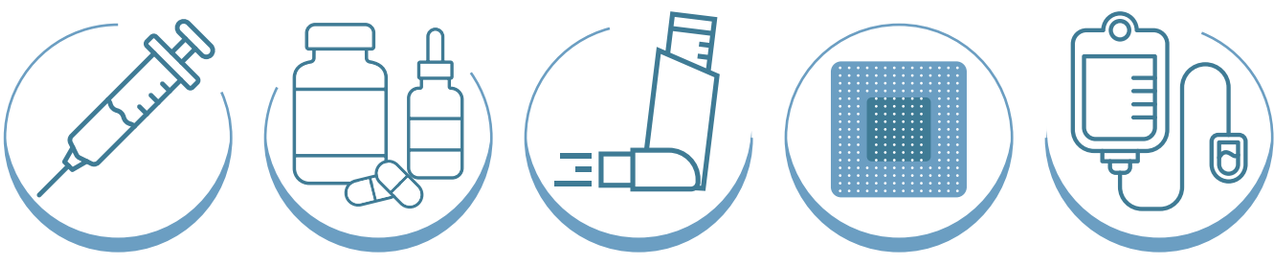
Custom programs for multiple modalities that conform to the latest regulatory guidelines

- 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

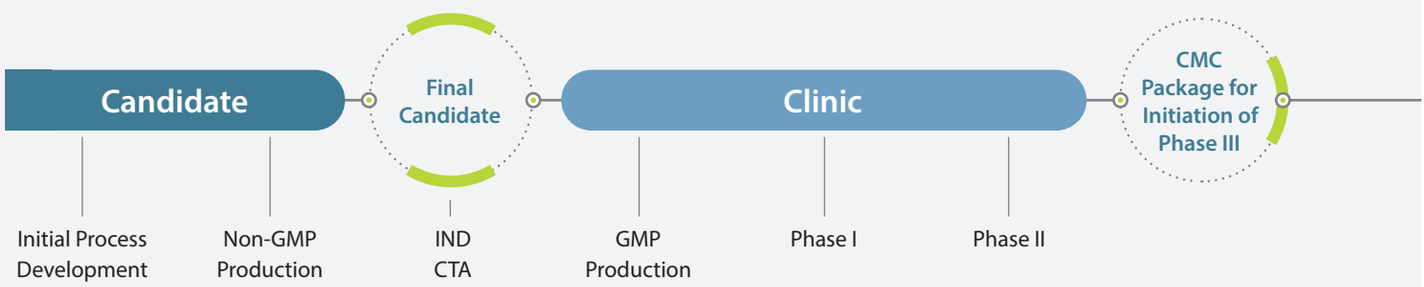


Parenteral Products | Oral Delivery | Orally Inhaled & Nasal Drug Products | Topical & Transdermal | Single-Use Systems

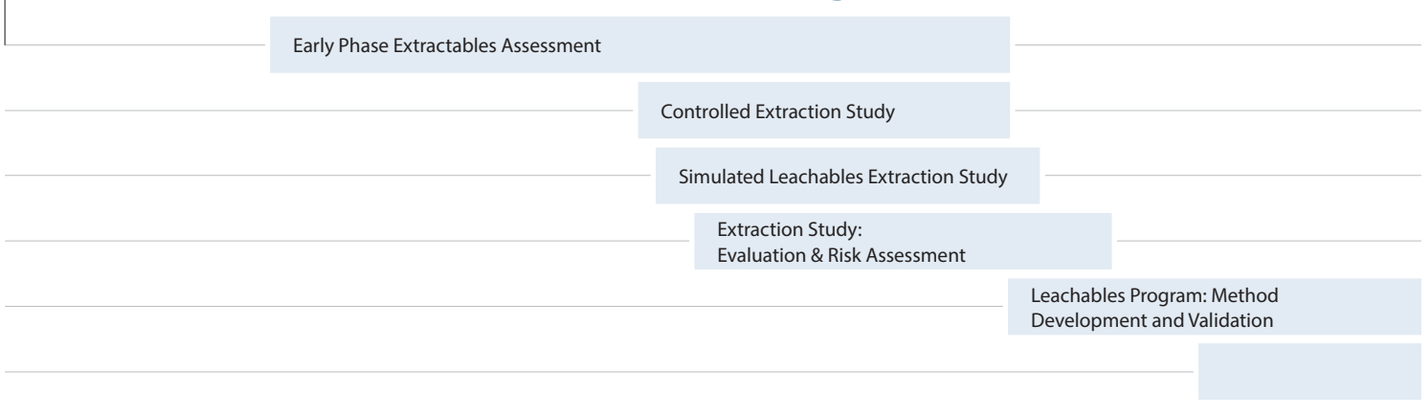
E&L data are a mandatory part of the submission package for regulatory approval

- Our team has extensive experience working with the **FDA and EMA regulatory agencies**
- Extensive experience with **USP & BPOG**
- 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

Product Development Process



Extractables & Leachables Program



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

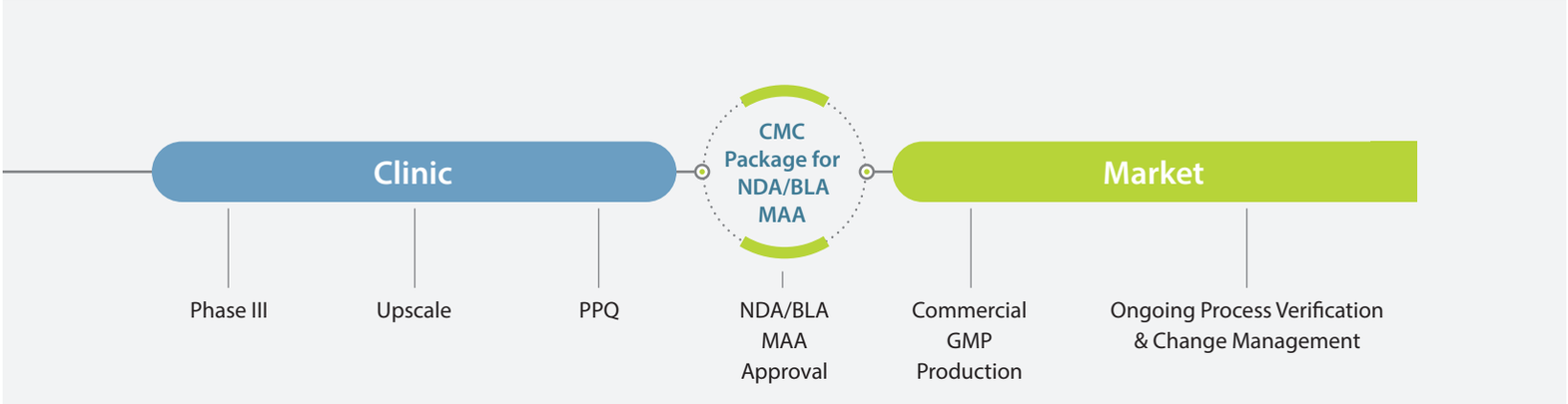
Expertise	**Risk based approach:** Study design requires expertise and careful cost benefit analysis. With years of experience and extensive regulatory knowledge, **we avoid common pitfalls and successfully manage highly complex studies using both simulated and custom design.**
	Our **structural elucidation 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
Technology	**Early adopters of HRAM** (high-resolution, accurate-mass) with both LC & GC methods
	HRAM extracts more information from samples and is especially important for compounds not in the commercially available public data bases
	With our technology and expertise, we can **identify and quantify compounds with extreme sensitivity**, enabling us to reach even the most challenging analytical evaluation thresholds (AETs)
Database	In addition to the publicly available data bases, Solvias has complied **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



Leachables Stability, Change Management, Leachables Release

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

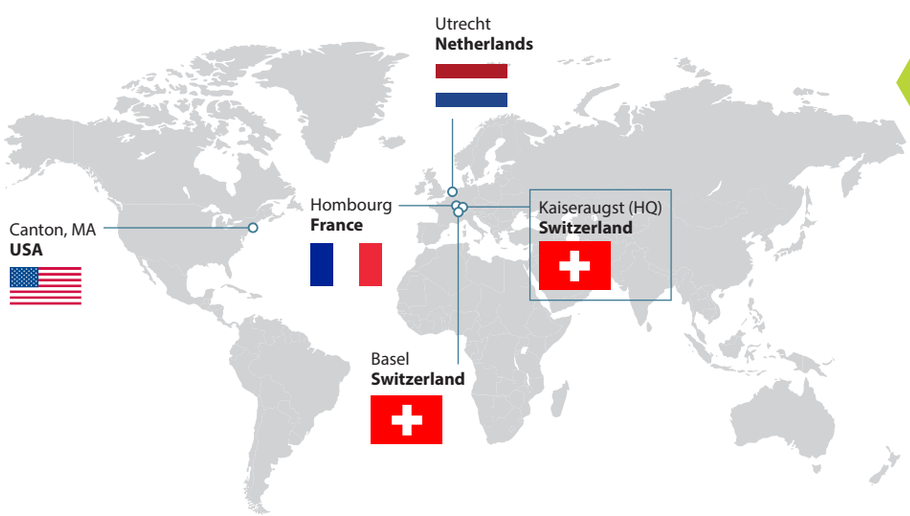
- Formerly Chemic Laboratories, LLC
- 30 minutes SW of Boston
- >2,000m^2 facility
- 9 FDA inspections (most recent Dec '22)
- Host ~20 client audits annually
- Controlled substance license for schedules 1–5
- Multiple DEA inspections

Kaiseraugst, CH

- 30 minutes SE of Basel
- >12,500m^2 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

Solvias Group

- CDMO/CRO founded in 1999
- 800+ FTEs
- 175+ PhD-level scientists
- GMP, GLP, ISO 9001 certified
- 700+ current customers
- 5 worldwide centers of excellence



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