



Solutions Synthesized



Presentation Senn Chemicals AG

- › 50+ years of Swiss tradition
- › Independent, family-owned
- › Certified
 - cGMP (manufacturing license Swissmedic)
 - ISO 9001:2008
- › Pioneered amino acid building block synthesis
- › Fmoc, Boc, Cbz protection
- › Specialized in peptide synthesis
- › Solution phase synthesis up to 2'500 L
- › Fmoc solid phase technology incl. prep HPLC and lyophilization
- › From grams to 100+ kg
- › Pre-clinical to commercial cGMP supply
- › Starting materials, key intermediates and APIs

Guido A. Senn in 1963



The early days

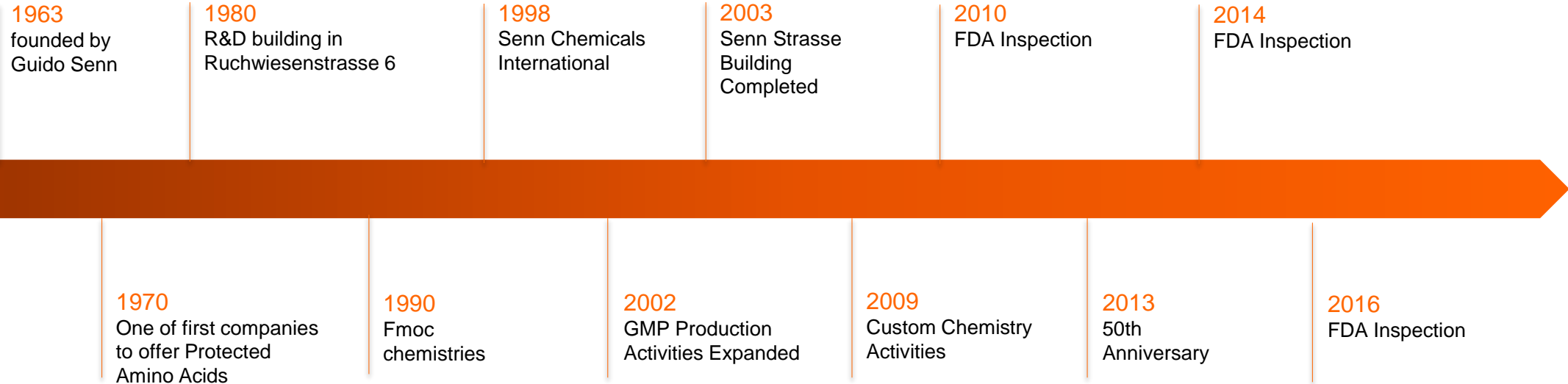
- › Founded in his garage in Dielsdorf (1963).
- › What began as a catalog business for carbohydrates and rare sugars evolved into a global custom peptides manufacturer serving pharmaceutical and biotechnology companies worldwide.



Solutions Synthesized

History of Senn

1963 | 2017







SENN Quality Control to achieve project goals:

- › Method Development
- › Method Qualification and Validation
- › Stability Studies
- › Qualified External Service Laboratories
- › Reference Standard Qualification



State of the art technologies in Quality Control:

- › Physical Characterization
- › Impurity Identification
- › Residual Solvent Determination
- › Pharmacopeia Testing
- › Chromatographic Assays
- › Spectrometry
- › LC-MS
- › LC-MS/MS
- › HPLC
- › GC

Qualified contract laboratories used for any additional analytics in agreement with the customer.

› **FDA**

- › May 2016 (GMP)
- › March 2014 (GMP)
- › July 2010 (PAI)
- › November 2002 (GMP)



› **Swissmedic**

- › August 2016
- › August 2014
- › August 2012



› **ISO 9001:2008 Re-certification**

- › 2017



› **Swiss Safety Audits: AWEL, SUVA, GVZ (Fire Protection)**

- › 2010, 2012, 2015, 2016

› Solid Phase Chemistry

- › Automated SPPS Reactors
- › CSBio (80/160 L, operated in GP site)
- › PTI Prelude
- › PTI Tribute
- › Activotec P11
- › Semi-automated SPPS Reactors (variable scales)
- › Lab Lyophilizer (Zirbus Technology, VaCo5)



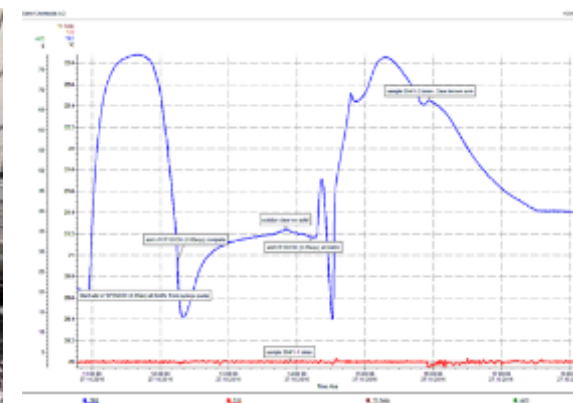
› Solution Phase Chemistry

- › Hydrogenators (0.1 L, 2 L, 20 L)
- › Low Temperature Reactor (20 L) down to minus 120 °C
- › Glass Reactors, jacketed (3 L, 6 L, 10 L, 20 L, 30 L)
- › 3 Automated Laboratory Reactors (FlexyCUBE, Systag)



› Purification Equipment

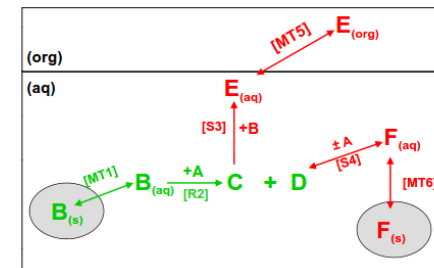
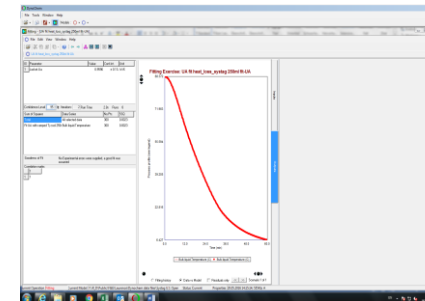
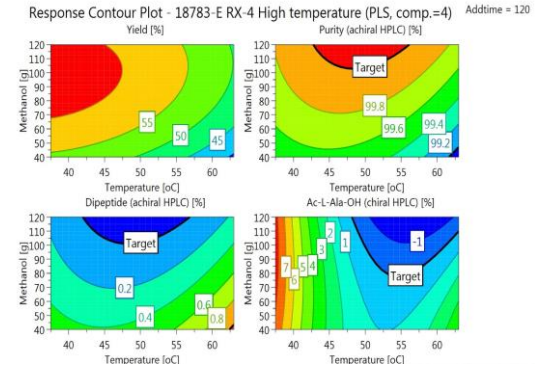
- › Preparative HPLC
- › Semi-preparative HPLC (AlphaCrom)
- › HPLC-Skid (3L/ min) (AlphaCrom) with 10 cm ID or 20 cm ID DAC column
- › Preparative MPLC
- › Automated Purification System (Teledyne Isco)



- › Modde 11 Pro
 - › Software for advanced DOE and quality analysis for development and manufacturing

- › Dynochem
 - › Process development and scale-up software

- › Britest
 - › Tools to define, structure, and translate working knowledge into process understanding





- **Multi-Purpose Reactors**
 - 100 to 2'500 L
 - - 20 to +120 °C
 - glass-lined, enamelled, Hastelloy, steel

- **Hydrogenation Reactors**
 - 100 to 2'500 L
 - Max. 6 bar

- **Filtration**
 - Filter nutsches (various sizes)
 - Pressure filter

- **Drying**
 - Vacuum tray driers (various sizes)

- **Solid Phase Reactors**
 - 80 to 160 L

- **Preparative HPLC Chromatography**
 - Production Skid (3 L/min)
 - 10 cm ID DAC column
 - 20 cm ID DAC column



- › Multi-Purpose Glass-Line Reactors
 - › 250 to 2'500 L
 - › - 20 to +120 °C

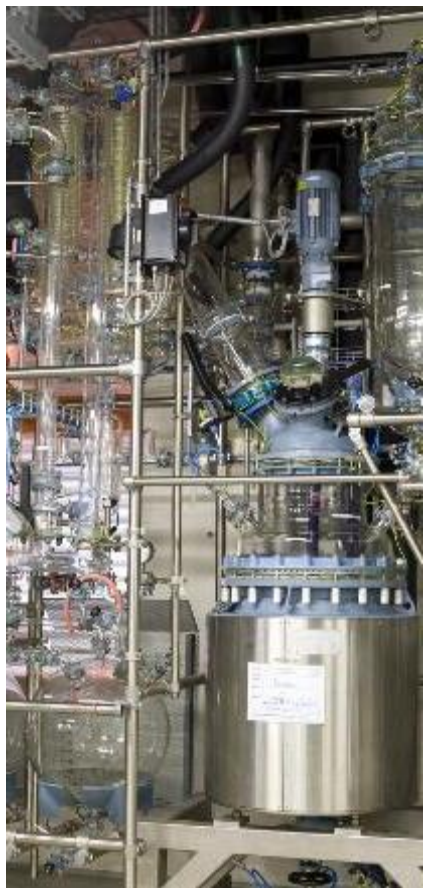
- › Hydrogenation Reactors
 - › 630 to 2'500 L
 - › Max. 6 bar

- › Solid Phase Reactors
 - › 80 to 160 L

- › Preparative HPLC Chromatography
 - › Production Skid (3nL/min)
 - › 10 cm ID DAC column
 - › 20 cm ID DAC column

- › cGMP Suites

- › Lyophilization



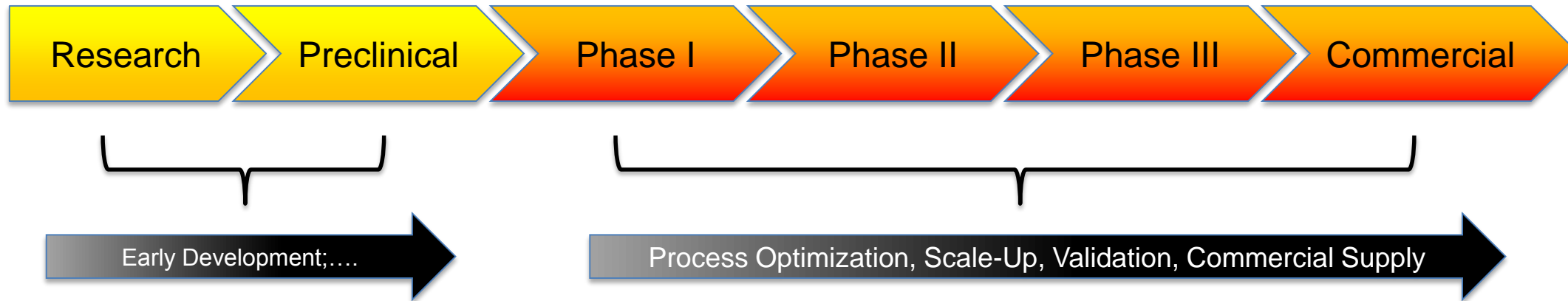
- › Acylation
- › Alkylation
- › Amidation
- › Amination
- › Aminoalkylation
- › Carboxylation
- › Condensation
- › Amide Coupling
- › Cyclization
- › Enzyme catalyzed reactions
- › Epoxidation
- › Esterification
- › Glycosylation
- › Grignard
- › Halogenation
- › Hydrogenation
- › Oxidation
- › Polymerization
- › Transesterification
- › ...

From early research to commercial phases



- › Route finding
- › Novel Process Development
- › Process Optimization
- › Analytical Method Development
- › Scale-up & Validation
- › cGMP Manufacturing
- › Commercial supplies to the pharmaceutical and cosmetic industries

From early research to commercial phases



- › Service according to all Preclinical and clinical phases
- › For intermediates and APIs
- › Fragments and Peptides
- › Project specific requirements upon final requirements and application



- › Dedicated Project Manager to our clients
- › Single point of contact and center of communication
- › Progress reporting
- › Knowledge of project details
- › Supervision from the evaluation to the final completion of deliverables



- › Coordination of a multi-disciplinary team
- › Monitoring of milestones and deliverables
- › Controlling timelines
- › Responsible for the success of the entire project

Preclinical through Commercial

- › Peptides
 - › Peptidomimetics
 - › Lipopeptides
 - › Glycopeptides
 - › Peptide Polymers
- › Amino Acid Derivatives
- › Carbohydrates
- › Small Molecules
- › Nucleotides
- › Resins

