

Position Specification



Title: Lead Chemist/Chemical Engineer

Opportunity: With the technical collaboration and/or direction of Professor Adam Heller (Chief Science Officer) and Phillip Plante (Vice President of Process Development), the Lead Chemist/Chemical Engineer will be a core member of synAgile's six-member management team providing technical leadership for its essential physical chemistry, chemical engineering, materials science, analytical chemistry, and pharmaceutical formulation. The chemist/chemical engineer will build his laboratory and work with his own hands, assisted as needed by a technician.

This unique position requires a highly creative individual with a passion for technology. The candidate is action-oriented and driven to solve unforeseen problems as they surface and to propose applications of synAgile's oral medication infusion technology. Passion and commitment to solve technical challenges aimed at improving lives of people are critical.

Education and Experience:

- BS, MS, PhD, or ScD in Chemistry, Chemical Engineering, Materials Science, or related field. *Educational level is less important than a demonstrated ability to think, combined with graduating at or very near the top of the candidate's class.* The candidate may join from academia or industry.
- Understanding of principles of chemistry, chemical engineering, and materials science including as many as possible of:
 - Physical chemistry: kinetics and thermodynamics, phase equilibria, kinetics of phase transitions, surface and interface phenomena.
 - Chemical engineering: heat and mass transport, fluid dynamics, mixing, filtration.
 - Materials science of polymers (plastics, adhesives, rheology); metals; composites; diffusion; diffusion barriers; bonding (welding, adhesion); ceramics; electron microscopy.
 - Analytical chemistry (HPLC, mass spectroscopy, particle size analysis).
- Pharmaceutical or medical product development experience preferred but not required.

Initial Tasks:

- Plan and implement synAgile's in-house chemistry activities.
- Engage and collaborate with outside experts to address emerging issues.

- Establish and operate a small analytical, physical chemistry and chemical engineering laboratory in support of synAgile's DopaFuse drug manufacturing for Phase 2 and Phase 3 clinical trials in order to:
 - Evaluate the chemical stability of synAgile's DopaFuse formulation.
 - Evaluate the physical stability of synAgile's DopaFuse formulation.
 - Formulate novel continuously orally infused medications.
- Under a GMP quality system, scale-up DopaFuse drug manufacturing to ~25 kg batch size.
- Creatively solve unanticipated problems in:
 - Phase transitions and equilibria.
 - Heat flow.
 - Mixing.
 - Slip (plug) flow.
 - Filtration.
 - Physical stabilization of suspensions and emulsions.
 - Assaying to establish chemical stability and chemical degradation mechanisms.
 - Design of analytical methods.
 - Formulation for oral and buccal drug delivery.
 - Toxicity.

**Expertise and
Personality:**

The successful candidate will:

- Have significant accomplishments in science, technology, and/or engineering - commensurate with his/her years of experience (if any) in industry and/or in academia.
- Be able to navigate changing priorities in a highly technical, scientific, and fluid environment.
- Analyze and interpret observations, deduce consequences, and address seemingly unsolvable problems.
- Be passionate about solving technical challenges.
- Be passionate about designing experiments.
- Be a keen observer and interpreter of experimental data.
- Know how to access and filter information from the scientific, technological and medical databases, to read and understand the publications retrieved usually by him/her-self, or when necessary, assisted by an outside expert that (s)he will identify.
- Easily identify problems and opportunities.
- Have a strong basis in as many as possible of:
 - *Physical chemistry*: including thermodynamics, e.g. phase transitions; physical stability of emulsions; heat flow (e.g., evaporative cooling); mixing for homogeneity; kinetics (e.g., diffusion in viscous media, diffusion through thin polymer and metal films); surface chemistry, wetting and tribology; corrosion electrochemistry; polymer chemistry; adhesion and adhesives.

- *Analytical chemistry*: measurement of particle sizes and particle size distribution; rheology; dissolution rates; HPLC; Karl Fischer assay of water content; and interpretation of FTIR spectra; interpretation of SEM images and data.
- *Chemical engineering*: heat and mass transport; mixing and mixers; fluid dynamics (non-Newtonian flow, slip (plug)-flow; polymer processing.
- *Materials science and engineering*: Strength of materials; metals; polymers and plastics; coatings; diffusion barriers; seals and sealing; bonding and adhesives.

The Company:

synAgile is an innovative drug delivery startup founded by Ephraim Heller (CEO) and Adam Heller (CSO). synAgile has developed the OraFuse® drug delivery platform for the continuous oral delivery of drugs with poor pharmacokinetics which cannot be delivered via conventional controlled release pills. OraFuse consists of a standard, clear, dental retainer carrying a miniature, disposable drug delivery device that continuously infuses medication into the mouth. synAgile's first product is DopaFuse®, which uses the OraFuse device to infuse a proprietary formulation of levodopa and carbidopa (LD/CD) into the mouth for the treatment of Parkinson's disease (PD). The LD/CD is swallowed with the patient's saliva and absorbed via the conventional gastrointestinal route. DopaFuse will enable patients with PD to achieve near-constant plasma levodopa levels and dramatically reduce their motor fluctuations. DopaFuse will be the first *noninvasive* system for continuous LD/CD delivery and represents a major improvement in the standard of care. A successful proof of concept clinical trial of continuous LD/CD delivery is complete and a Phase 2 trial of the DopaFuse system is scheduled for 2019.

Ephraim and Adam were previously the founders of TheraSense, a glucose monitoring company sold to Abbott for \$1.2 billion. After TheraSense, Ephraim was the founding CEO of AngioScore, a balloon angioplasty company acquired by Spectranetics for over \$230 million. Prior to TheraSense, Adam was the co-developer of one of the first commercial primary lithium batteries. He is a professor at University of Texas at Austin and a recipient of the US National Medal of Technology and Innovation, the top technology award in the United States. The senior management team has an established a successful track record of start-up company building - commercial product launch and exit - that have provided both rich ROI and solutions to major patient populations.

Management Team:**Ephraim Heller, Founder & CEO**

Ephraim Heller is the Founding CEO of synAgile. Ephraim was Founding CEO of AngioScore Inc., a balloon angioplasty company acquired by Spectranetics for over \$230 million in 2014. Before that, he was Founding CEO and later VP of Marketing and VP of Business Development at TheraSense Inc., a maker of blood glucose monitoring systems for people with diabetes. TheraSense went public in 2001, sales grew to \$270 million in 2003, and the company was acquired by Abbott for \$1.2 billion in 2004. Ephraim holds over 100 issued US patents. He received a BA in Physics from Harvard and an MBA from Yale.

Adam Heller, Chief Scientific Officer

Adam Heller is synAgile's Chief Scientific Officer and a professor of chemistry, chemical engineering, and materials science at the University of Texas at Austin. At GTE Research, Adam and his colleague Jim Auburn conceived and codeveloped the first commercialized lithium thionyl chloride battery, a product that has sold billions of units. At AT&T Bell Labs, Adam headed the department that developed manufacturing processes for high-density chip interconnections. He cofounded TheraSense with Ephraim and served as its CTO, leading development of a product that has again sold billions of units. He holds over 250 issued US patents. Adam received his doctorate from the Hebrew University in Jerusalem and is regarded as one of the top bioelectrochemists of the world. He was elected to the National Academy of Engineering and received numerous prestigious awards, including the 2008 US National Medal of Technology and Innovation, the top technology honor of the United States.

Phillip Plante, Vice President of Process Development

Phillip Plante is synAgile's VP of Process Development. Phil has over 30 years' experience working individually and on teams in developing medical products and processes. Phil scaled up commercial manufacturing of the original One Touch diabetes test strips for LifeScan, a variety of critical care products for Oximetrix (Abbott Critical Care Systems), a cholesterol diagnostic for ChemTrak, a variety of drug delivery & diagnostic products for Cygnus Therapeutic Systems, and the FreeStyle diabetes test strips for TheraSense (Abbott Diabetes Care), among other products both medical and non-medical. Phil has a BS in Chemical Engineering from MIT.

John Spiridigliozzi, Vice President of Device Development

John Spiridigliozzi is synAgile's VP of Device Development. John has over 20 years of experience and a proven track record of solving complex engineering problems for early stage and established medical device companies. John most recently served as Director of Engineering with NeoGraft Technologies, where he helped develop a novel system for the treatment of saphenous vein grafts for bypass surgery. Prior to that, John served as VP of Product Development with Sonitus Medical where he developed the first hearing assist device to transmit sound via the teeth. John holds over 40 issued US patents. John received a BS in Mechanical Engineering from Northeastern University.

Jennifer Harmon, Director, Clinical Affairs

Jennifer Harmon is Director, Clinical Affairs at synAgile. Jennifer leads the development and implementation of SynAgile's clinical trials including regulatory and trial oversight functions. Based in Singapore, Jennifer is also the key liaison for business operations in Asia. From 2009-2017, Jennifer worked at Duke-NUS Medical School Singapore, which opened in 2006. She was Associate Director at the Centre of Regulatory Excellence, which aimed to strengthen regulatory systems in the Asia Pacific region. Prior to that, she provided in-house clinical trials consultation for clinicians and research units across the SingHealth-Duke-NUS Academic Medical Centre. She founded the AMRI Research Professionals organization, which has reached more than 400 research staff. From 2002-2009, Jennifer worked at the Moran

Eye Center, University of Utah. Under the leadership of Dr Kang Zhang, she conducted clinical trials in genetics of eye diseases, and co-authored 11 papers.

Taung Lau, Director of Quality Assurance

Taung Lau is synAgile's Director of Quality Assurance. Taung has over 20 years of experience as an individual contributor and technical leader in quality assurance and quality engineering. Most recently, Taung was Director of Quality Assurance for Ouroboros Medical, acquired by J&J, where he led efforts to obtain ISO certification, quality system and CE approval. Previously, Taung was Director of Quality for Biomerix Corporation, where he successfully managed quality systems including audits, document control, monitoring nonconformance and corrective actions, training, and management review. Taung received a BS in Integrative Biology from the University of California at Berkeley and a MS in Industrial Systems Engineering from San Jose State University.

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