

Sebastian Kharileh, M.Sc.

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SUMMARY

Biomedical engineer with M.S. training and experience in drug delivery research, medtech startup operations, and project coordination. Proven ability to accelerate development timelines, support regulatory compliance, and drive cross-functional execution in fast-paced environments. Brings hands-on R&D and laboratory expertise, process discipline, SOP and publication drafting experience, and strong team leadership experience.

SKILLS & CERTIFICATIONS

Laboratory & Regulatory: Drug delivery systems synthesis, PLGA microparticle synthesis, mammalian cell culture, sterile technique, spectrophotometry, DLS, SEM imaging, lyophilization, gel electrophoresis, mechanical testing (Instron), GLP, GCP, ISO 10993, ISO 13485, FDA Sections 351 & 361

Software & Research Tools: GraphPad Prism, R, ImageJ, LabSuit, SolidWorks, Cadence Virtuoso, Python, MATLAB

Certifications: AI in Pharma & Biotech (MIT Sloan School of Business, 2026), Fundamentals of GCP (Novartis, 2025), Engineering Innovation (University of Florida, 2024), Sigma Yellow Belt (CFQ International, 2021), Eagle Scout (BSA, 2013)

EXPERIENCE

Operations Consultant | Epinal, Irvine, CA | **May 2025 – Present**

- Sole biomedical engineering SME, overseeing NarcoLyzer development tracking, FDA compliance, and SOP drafting across all current development activities
- Orchestrated incubator outreach and partnership development to establish lab space for prototype assembly, positioning the team for validation testing
- Expanded industry visibility by 20% through targeted conference and trade show submissions, growing the company's partnership pipeline and industry presence

Project Associate | Silicon Artist, Irvine, CA | **Sept 2024 – May 2025**

- Delivered Newport ASIC Quadrant 1 ahead of schedule by optimizing schedule tracking, dependency management, and engineering resource allocation
- Accelerated delivery timelines by four weeks by leveraging Microsoft Project to map the critical path and collaborating with the engineering team to reallocate resources, eliminating bottlenecks before they materialized

Graduate Research Assistant | The Taylor Lab, University of Florida, Gainesville, FL | **Oct 2021 – July 2024**

- Engineered a polymeric dual-biofactor drug delivery platform with tuned release kinetics to support tissue regeneration
- Tailored biofactor release across 21 days, aligning delivery with the biological milestones of tissue regeneration
- Characterized microparticles via SEM, DLS, and ImageJ and maintained SOPs and documentation necessary for reproducibility and audit readiness
- Reduced equipment costs by 90% by designing and fabricating an in-house electrospinning system, delivering a resource that became central to the lab's broader research efforts
- Established and enforced lab safety standards as the Environmental Health & Safety liaison, ensuring full GLP compliance across all lab projects

PUBLICATION

Temporally controlling the release of biofactors from polymeric microspheres. *MRS Communications* **14**, 927–934 (2024). DOI: 10.1557/s43579-024-00600-0

EDUCATION

University of Florida | Gainesville, FL | **2024**

Master of Science, Biomedical Engineering

Rutgers University | New Brunswick, NJ | **2021**

Bachelor of Science, Biomedical Engineering