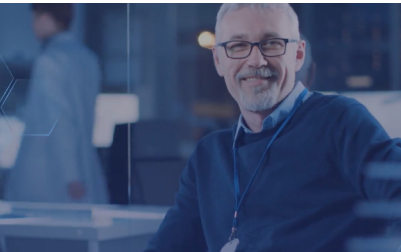


KYMANOX EXECUTIVE ADVISORS

The Kymanox® Executive Advisor (KEA) team provides strategies, guidance, and leverages our deep relationships in the global life science industry to help build your company and products. We can help ensure your success from business creation through all phases of development and commercialization.



KEA Services

Kymanox Executive Advisors are well-known and seasoned executives who have deep expertise building businesses, capabilities, and bringing products from inception through commercialization in the pharmaceutical, biotechnology, and medical device industries. The prestigious members of this advisory are able to utilize their vast expertise, particularly in the areas of combination products, connected devices, and pharmaceutical manufacturing. The focus of the KEA team is to provide guidance and strategic thinking, foster valuable relationships, and identify additional resources to help your project be successful.

KEA Expertise

Strategy Development and Planning

- Business start-up, scale-up and organizational growth
- Operations and commercialization
- Human factors and regulatory affairs
- Connected and digital health
- Intellectual property development
- Market intelligence and product placement
- Product strategy and road mapping
- Strategic risk identification and mitigation
- Due diligence assessments.
- International market expansion and life cycle management

Combination Product Expertise

- Design, development and commercialization of drug/device combination products
- Platform selection and identification of new innovation
- Component selection and supply chain analyses
- Oversight to ensure program success
- Support for negotiation and expectations with proper Contract Development and Manufacturing Organization (CDMO) and supplier selection
- Business and regulatory risk mitigation



Kymanox®

www.kymanox.com

**Fran DeGrazio: 35+ years of experience in the pharmaceutical packaging and delivery industry**

- Extensive expertise in sterile drug product systems, including vial container closure systems and prefillable systems for combination products.
- Published numerous technical articles and book chapters.
- Recipient of the PDA Packaging Science Award for 2021, Philadelphia Business Journal 2018 Healthcare Innovators of the Greater Philadelphia Region Award, and the Healthcare Businesswoman's Association Luminary Award for West in 2017.

**Paul Jansen: Professional Engineer with 30+ years of experience in medical devices**

- Extensive experience in the design, development, manufacturing, and lifecycle management of medical devices.
- Has successfully led teams that have developed and launched several award-winning devices, including Lantus SoloStar, the world's most popular insulin pen injection device.
- Long-time member of the International Standards Organization serving as Working Group Convenor and Expert on many work groups responsible for standards related to injection devices.

**Mathias Romacker: 30+ years of experience in injectable drug delivery devices**

- Solid understanding of the markets for prefilled syringes, handheld injection devices, and wearable devices and has been involved in multiple successful product launches with combination products.
- Co-chair for PDA conferences 'Universe of Pre-filled Syringes and Injection Devices' in Basel in 2013, Vienna in 2017, Gothenburg, Sweden in 2019, and in Palm Springs, CA in 2022.
- Recipient of the PDA 'Edward Smith Packaging Science Award' in 2018 for his contributions over the years.

**Stephen M. Perry: Founder and Chief Executive Officer at Kymanox**

- Two decades of experience in biopharmaceutical manufacturing with an emphasis on design engineering, scale-up, start-up, and regulatory approval.
- Has participated in the FDA commercial approval of more than two dozen unique drugs, devices, biologics, and combination products
- Has led numerous multi-million-dollar capital projects and has contributed to several major facility installations and qualifications, which began at the conceptual design phase.

**Evan Edwards: Chief Development Officer at Kymanox**

- Subject matter expert in Usability Engineering, Design Controls, Combination Products, Operations, Industrialization, Quality Systems, Executive Leadership, Pre-Approval Inspection Readiness, Human Factors, Intellectual Property Strategy and Invention and Design.
- Named on over 200 patents, issued and pending, both domestically and abroad.
- Co-founder of kaléo Inc. and co-inventor of the AUVI-Q (epinephrine injection, USP) and kaléo's drug delivery device technologies.

**Michael Denzer: Vice President of Technical Solutions at Kymanox**

- Seasoned life science executive who blends a wide range of commercialization experience with strong interpersonal and communication skills.
- Expert in all aspects of combination product development in the USA and Europe and holds multiple patents in regards to injector (parenteral) devices.
- Passionate about bringing meaningful medical treatments to as many patients as possible.