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KLK Kolb



The annual listing of 10 companies in Europe that are at the forefront of providing Pharma Manufacturing solutions and transforming businesses in the region

KLK Kolb

Quality Commitment in Pharmaceutical Processes for Swiss-crafted excipients

KLK Kolb, headquartered in Switzerland, epitomises innovation and excellence within pharmaceutical manufacturing. It is a leading manufacturer of non-ionic surfactants. The firm's dedication to delivering superior health solutions out of its manufacturing site in Hedingen (Switzerland) is evident in its pursuit of quality and understanding of the industry's evolving landscape.

Dr. Daniel Mattle, Director Pharma Solutions, emphasises the company's approach, stating, "We implement rigorous processes across all our products to minimise impurity profiles and cross-contaminations" KLK Kolb's products are well-established in pharmaceutical formulations as excipients in drug products, process aids during purification steps, in diagnostics, and in many biotechnological processes.

KLK Kolb transcends traditional pharmaceutical excipient production, establishing itself as an indispensable partner in healthcare. By delivering excipients integral to life-saving drugs and essential medications, the company signifies its pivotal role in the industry. KLK Kolb's commitment to quality is evident through its stringent manufacturing and testing procedures, alignment with ISO 9001 and GMP EXCiPACT Certification, and adherence to IPEC PQG Good Manufacturing Practice (GMP) guidelines. The company documents every stage of manufacturing and quality control, ensuring superior quality in excipient production and meeting customers' diverse needs.

Addressing the challenges pharmaceutical manufacturers encounter, especially in selecting optimal excipients, KLK Kolb introduces its Hedjuvan portfolio. Crafted in Switzerland, this portfolio is underpinned by a comprehensive quality and regulatory product dossier, indispensable for drug product filings and adeptly handling inquiries from global regulatory bodies, including the FDA, EMA, and China's NMPA. Demonstrating agility, KLK Kolb frequently updates this dossier, staying abreast of industry trends and regulatory shifts.

Renowned for expertise in contract development and manufacturing, KLK Kolb is the quintessential partner for creating custom excipients that precisely match customer specifications. The swiss-made Hedjuvan brand serves a

wide spectrum of applications across human and veterinary pharmaceuticals, as well as in biopharmaceutical sectors. The company proactively registers its excipients with pertinent authorities in China and Europe. This ensures comprehensive access to essential documents like CEPs and DMFs, promoting a compliant and holistic operational framework.



Dr. Daniel Mattle,
Director Pharma Solutions

In response to growing concerns about contaminations in over-the-counter medications, KLK Kolb has escalated its commitment to patient safety and product quality by instituting rigorous analytical assessments. These measures

effectively mitigate potential risks, emphasising the company's dedication to surpassing the industry's standard requirements. KLK Kolb's approach to quality assurance ensures transparency and adherence to regulatory requirements through registration of excipients and the provision of essential documentation.



Hedjuvan-PS20 and Hedjuvan-PS80, products of KLK Kolb, have emerged as a pivotal contributor to the advancement of innovative biological drugs aimed at combating cancer and stroke. This versatility is not confined to medical treatments; the Hedjuvan brand also finds extensive application in a range of over-the-counter products, including drops, ointments, creams, and eye drops. Recognised as an exemplary solubiliser and carrier for active pharmaceutical ingredients (APIs), the product line enhances these products' efficacy, thereby profoundly impacting patient care.



We implement rigorous processes across all our products to minimise impurity profiles and cross-contaminations

Navigating the complexities of the biopharmaceutical and contract manufacturing industries presents formidable challenges, especially in managing the extensive qualification process for the myriad suppliers. Major pharmaceutical entities typically engage with over 4,000 suppliers, necessitating a rigorous and periodic requalification routine. In recognition of this intricate landscape, KLK Kolb has proactively embraced the

EXCiPACT certification. This facilitates the use of third-party audits, recognised by regulatory bodies and ensures the involvement of a reputable certification entity, streamlining the qualification process.

KLK Kolb's commitment to quality and safety is further underscored by the analytical data assessments conducted for the majority of its products. Besides standard tests, Kolb is also committed to analytics according to ChP, microbial testing and current topics like DEG/EG that are part of the CoA. This approach focuses on managing and controlling supplier-related risks, prioritising patient-centric outcomes over mere customer satisfaction.

In addition, the company has notably advanced its quality control protocols by developing a method to measure dioxane content more precisely, exceeding global regulatory standards and monographs. This innovation was catalysed by a client's need for lower dioxane levels, diverging from the usual certificate of analysis based on universal pharmacopoeia standards. Collaborating intensively with the client and contract manufacturing analytical laboratories, KLK Kolb formulated and implemented a tailored process, meeting specific market requirements with a bespoke certification.

Parallel to these technical achievements, KLK Kolb proactively addresses environmental concerns. KLK Kolb is committed to reducing CO₂ emissions by 30 per cent by the end of 2030 and ensures that its raw materials, final products, and processing aids adhere to green chemistry and sustainability principles. If desired, Product Carbon Footprints can be delivered for each product; and ecolabel information are also available.

KLK Kolb's products exhibit remarkable versatility, reaching beyond human health to contribute to animal health, bioprocessing, and blood purification. The company's role in formulating disinfectants and diagnostics underscores KLK Kolb's adaptability and effectiveness of its products across diverse industries and sectors. 🇨🇭