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CORDENPHARMA

EXPERTS TAKING CARE

CORDENPHARMA

US

YOUR EXPERT PARTNER

2006
Formed as the pharmaceutical brand of International Chemical Investors Group (ICIG)

Full-service CMO

CordenPharma is your full-service CMO partner in the Contract Development & Manufacturing of pharmaceutical Drug Products, their Active Pharmaceutical Ingredients (APIs), and associated Packaging Services. Our network of world-class cGMP facilities and team of experts acquired from top pharmaceutical and biotechnology companies across Europe and the US provide you with effective outsourcing spanning all phases of pharmaceutical development from R&D to Commercialization. At Cordenpharma, our experts are taking care to follow your needs every step of the way.

* All photos were taken at CordenPharma facilities in Europe and the USA

- Multiple cGMP Facilities across Europe and the USA, each with >25 Years of Experience
- >1600 Employees
- >100 Experts in QA/QC/RA Teams Globally
- Dedicated Project Management Teams
- 2012 Revenues: >€ 250 mm

YOUR PATH TO BALANCED OUTSOURCING

Today, with approximately 1,600 expert employees, 2012 revenues of >€ 250 mm and a combined facility legacy of over 200 years of established success, CordenPharma is your full-service CMO partner in creating flexible, efficient solutions for all your outsourcing needs. We utilize a broad range of technologies, products, and services - from APIs to Drug Products - spanning all phases of development and commercialization. Your pharmaceutical projects will benefit from our adherence to the highest standards of quality and service.

EXPERTS TAKING CARE

We understand that behind every successful pharmaceutical project are the people, from the chemists and operators to the QA/QC teams, project managers, and most importantly customers, working together who make it possible. At CordenPharma, our experts are committed to providing you with inspired global service, regulatory support and dedicated project management at all points along your outsourcing path.

OUR HISTORY

CordenPharma was formed as a private pharmaceutical brand of International Chemical Investors Group (ICIG) in 2006 through acquisitions of multiple cGMP facilities across Europe and the US from top pharmaceutical and biotechnology companies.

ICIG

International Chemical Investors Group (ICIG) is a privately owned industrial holding company founded in 2004 which focuses exclusively on long-term investments of mid-sized chemical and pharmaceutical businesses with origins in major global chemical or pharmaceutical corporations. *Visit www.ic-investors.com for more information.*

OUR MISSION

CordenPharma is a full-service Contract Manufacturing Organization partner linking together a legacy of high-caliber scientists, technologies and capabilities in the development and manufacturing of APIs, Drug Products and associated Packaging Services to help leading pharmaceutical and biotechnology companies achieve their product success for their patients' healthier lives.

Solving Your Complex Problems
Through our long-standing experience in top big pharmaceutical and biotechnology companies, we understand the pharmaceutical industry's ever-changing variables - such as under-utilized capacity, fierce price competition, and growing regulatory pressures - which affect your pharmaceutical drug development. As your partner, we draw upon that insight to solve complex problems early-on and bring efficiency throughout the process.

- >60 APIs Manufactured
- >40 Commercial Drug Products Manufactured Yearly
- >50 DMFs Filed
- >300 Customers in 80 Countries

FROM APIs TO DRUG PRODUCTS CMO

>50 New Projects Annually

From R&D to Commercialization

CordenPharma provides a broad range of capabilities in the development and manufacturing of APIs and Drug Products. Spanning all phases from R&D to Commercialization, our network of fully-inspected cGMP facilities with adaptable volumes, state-of-the-art technologies and stringent quality systems provides flexible solutions to overcome the challenges often associated with outsourcing. We bring a more efficient balance to your outsourcing process by reducing the need for repeated technology transfer and management of fragmented supply chains and diversified best practices from multiple suppliers. Your customized set of complementary technologies in small and large-scale API production, drug product formulation development and manufacturing, primary and secondary packaging and pharma-logistics services will reduce overall development time to market while at the same time exceed the standards required for your product success. Contracted customers have also come to rely on our integrated project management and regulatory teams with strong experience in analytical, validation, and filing support.

APIs

No matter where you are in outsourcing APIs on the development path from R&D to Commercialization, your project will benefit from CordenPharma's breadth of capabilities in manufacturing APIs.

API DEVELOPMENT

CordenPharma's scientists have the experience to meet a wide range of API development needs from the custom synthesis of small to larger quantities (<10 kg to >250 kg) of your target compound and scale-up of an existing route, to identification and development of new and proprietary manufacturing routes with adaptable and scalable processes, including statistical design of experiments (DoE), real-time reaction monitoring, and reaction calorimetry. At each step of the process development cycle, complete hazard assessment tools are available to allow for safe production of your compounds.

API CUSTOM MANUFACTURING

We are linking together a legacy of reliable, effective cGMP API Contract Manufacturing to support your small and large-scale projects. Our technical manufacturing capabilities span a wide range:

- *Reactors pools with high flexibility in size (100-18,000L) and temperature (-100°C to +200°C)*
- *Multiple product isolation technologies (centrifuge, filters) with wide material compatibility (Hastelloy; stainless steel)*
- *Multiple drying options (agitated and static dryers)*
- *Multiple powder handling and finishing capabilities including sieving, blending and milling*
- *Handling of highly potent compounds down to exposure limits of 1ng/m³*

HIGHLY POTENT APIs

CordenPharma produces highly potent intermediates and APIs, including small volumes of highly potent peptide APIs, for commercial use. With containment safety systems and procedures suitable for the production of highly potent compounds with Occupational Exposure Limits (OEL) as low as 1 ng/m³, our high potency manufacturing and HPLC capabilities include flexible capacity with multiple filtration and drying options.

GENERIC APIs

For generic drug companies, we manufacture and supply over 50 proprietary Generic APIs (including controlled substances) for various indications. By using complex chemistry and technical expertise, we work with generic drug companies well in advance of drug patent expiration to provide non-infringing processes and file Drug Master Files (DMF) or Certificates of European Pharmacopoeia (CEP) for the APIs.
See our Generic API List for more information.

STERILE APIs

CordenPharma provides customers with dedicated technologies such as aseptic technique for the production of sterile APIs. Our sterile manufacturing facilities are comprised of chemical processing, sterile filtration, crystallisation, isolation, drying and powder treatment, as well as blending with sterile excipients. Sterile cephalosporins and penicillins are manufactured in dedicated manufacturing lines with a total vessel capacity of up to 32,000L and 25,000L respectively.

SYNTHETIC PEPTIDES

CordenPharma has the largest capacity for the synthesis and purification of peptides in the world due to being the only company to have produced metric tons of the complex peptide Fuzeon® (enfuvirtide). As the volume leader in custom peptide production with various automated peptide synthesizers ranging from 12L to 10,000L for solid-phase peptide synthesis, CordenPharma is committed to addressing complex solvent handling, recovery and recycling logistics.

With preparative HPLC, lyophilization equipment as well as proprietary peptide precipitation know-how for cost effective final-step peptide isolation, CordenPharma additionally provides expertise in scaling complex peptides with multiple disulfide bridges or particularly long sequences (up to 60 amino acid residues) as well as producing lipo and carbohydrate conjugates.

API BUILDING BLOCKS

CordenPharma is a recognized leader in the development and production of highly advanced building blocks such as (non-) natural amino acid derivatives (Fmoc-protected AADs and unusual AADs), nucleoside building blocks, API chiral building blocks (like alcohols and hydroxyesters) as well as the first worldwide supply of pseudoproline dipeptides (serine, and threonine derived Fmoc protected building blocks).
See our Pseudoproline List for more information.

CONJUGATE PRODUCTS

CordenPharma combines specialized core competencies in both cGMP synthetic peptide and lipid production with world-class regulatory and analytical support to become a distinguished supplier in the manufacturing of therapeutic lipopeptides at various chemical stages from discovery to commercialization.

CARBOHYDRATES

As a custom supplier of intermediates, CordenPharma meets a growing demand for carbohydrate-derived building blocks from which a variety of more complex oligosaccharides can be constructed. Our extensive experience includes carbohydrate chemistry and multi-kg manufacturing of innovative carbohydrate products to be used as monosaccharide building blocks and conjugates such as glycolipids, phosphatidyl inositols and glycopeptides.
See our Carbohydrates Brochure for more information.

DERIVATIZED PHOSPHOLIPIDS

CordenPharma's scientists have mastered the total chemical synthesis of complex fully synthetic phospholipid derivatives on a large cGMP scale. In addition, CordenPharma pioneered the chemistry and large-scale manufacture of MPEG-conjugated phospholipids and standard cationic phospholipids (such as DODMA and DOTAP available in cGMP and R&D grade qualities).

CordenPharma also supplies cGMP contract manufacturing of proprietary phospholipids, monoglycerols, diacylglycerols, sphingosines, ceramides and engineered cationic lipids, with a unique specialty in synthesizing novel liposome conjugate components conjugated with functional peptides or carbohydrates for targeted drug delivery.

A wide selection of readily available small pack phospholipids in 1g and 10g pack sizes suitable for R&D is also available for purchase.
See our Lipids List for more information.


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DRUG PRODUCTS

CordenPharma develops, formulates and manufactures Drug Products at all phases. Our specialized technologies and network of state-of-the-art facilities offer a wide range of capabilities with flexible solutions.

DRUG PRODUCTS

CordenPharma has a long history of developing, formulating and manufacturing Drug Products for customers at all phases in the drug development process. Our specialized technologies and network of state-of-the-art facilities offer a wide range of capabilities with flexible solutions for the success of your product.

DRUG PRODUCT DEVELOPMENT

CordenPharma's pharmaceutical Drug Product Development starts with the screening and optimization of suitable formulations and processes to best meet the defined target product profile and ensure reliable manufacturing by a robust, efficient and continuously improving process according to DOE concepts. During scale-up, critically defined and verified parameters with appropriate control strategies ensure that quality attributes are consistently met for validation during routine manufacturing.

CordenPharma's capabilities to support your Drug Product Development include:

- *Sterile emulsions and solutions*
- *Lyofilised oncology products (up to OEB5)*
- *β-lactams in solid and sterile powder forms*
- *Solid dosage forms:*
  - *Standard compounds in capsules and tablets*
  - *Oncological solid forms (up to OEB5) in capsules and tablets*
  - *Higly potent compounds (up to OEB 4/5) in capsules and tablets*
  - *Two-layer tablets*
  - *Capsule filling with different components (e.g. granules + tablets)*

DRUG PRODUCT CONTRACT MANUFACTURING

We draw upon a combination of facilities equipped to manufacture both solid dose and parenteral formulations of standard, highly potent, cytotoxic compounds, cephalosporins and penicillins.

Handling of sterile powder-filled vials, lyophilized vials, oral suspension powders, and injectable liquids is offered as well as specific techniques such as sterile emulsion technology, two-layer tablets, and the filling of capsules with powder granules or microtablets.

PARENTERALS

CordenPharma has a long track record of experience in the highly sophisticated manufacturing of parenteral sterile emulsions and solutions in various pharmaceutical forms such as ampoules, vials and large pre-filled syringes. Our filling lines are fully and semi-automatic (integrated including washing, depyrogenation, plunger insertion, filling, stopper insertion and crimping). Our automatic inspection lines support the highest standard requirements.

HIGHLY POTENT SOLIDS

Besides manufacturing standard compounds in tablets and capsules, CordenPharma meets the pharmaceutical industry's recent demand for more complex and potent compounds with more than 25 years of experience in handling highly potent non-cytotoxic formulation products up to level OEB4 (e.g. hormones, hormone blockers, oncology), and cytotoxic formulation products up to level OEB5. Our fully-contained sites, with high-volume equipment for granulation, drying, compression and tablet coating, as well as state-of-the-art PPE designed for flexible use in smaller batch sizes, produces capsules, film-coated and uncoated tablets, and two-layer tablets (in a wide variety of shapes).

CYTOTOXIC

For sterile formulations, our cGMP manufacturing facilities have a classified and independent building dedicated to aseptic processing in compliance with the FDA aseptic guidance and EMA regulatory requirements to minimize biological contamination. A combination of equipment design and fully qualified personnel (trained in aseptic techniques for Japanese quality standards) is pivotal to our success in the sterile filling of liquids and lyophilized products for cytotoxic oncologic compounds up to OEB5.

BETALACTAMS: CEPHALOSPORINS & PENICILLINS

For more than 20 years we have produced cephalosporin and penicillin formulations in a dedicated building. Sterile filling of powders and manufacturing of tablets, capsules and oral suspensions each with dedicated packaging lines are ready to support your requirements in terms of capacity, quality standards, flexibility and complexity management.

PACKAGING

With more than 20 years of experience in primary and secondary packaging, CordenPharma's packaging services start during development, where we investigate the optimal packaging material and process for our customers' intended handling and provide adequate protection of the drug product at desired storage conditions. Our highly flexible capacity of packaging lines guarantees maximum efficiency, quality and speed in processing from design and creation to delivery.

Customers have come to rely on our wide range of primary and secondary multi-product blister packaging services on 11 modern blister lines equipped with all standard blister materials (PVC/PVDC, Triplex, Alu/Alu, PP/Alu) including, but not limited to, laser printing, foil, pack serialisation / 2D Matrix printing (for anti-counterfeiting), handling of moisture-sensitive products at <20% RH, and vignettes (e.g. Bollini for Italy).

CordenPharma is additionally equipped with bottle filling for both standard and highly potent compounds including oncologicals, penicillins, and cephalosporins. Multi-vial and single-vial packs are available for injectable products.
We supply primary packaging of highly potent compounds up to OEB5 with the expertise and specific quality requirements needed for packaging in the Japanese market. Complexity is handled on a daily basis at CordenPharma, where we supply packaging in over 80 countries annually, including highly fragmented markets.
See our Packaging Brochure for more information.

PHARMA-LOGISTICS

CordenPhama provides modern, highly flexible warehouses and distribution centers for all your pharma-logistics needs. In addition to ensuring that all domestic shipping activities run smoothly, we arrange exports – including all customs formalities – both within Europe (Eastern Europe in particular) and worldwide.

CordenPharma is an experienced freight shipping company managing all transports (including hazardous materials) by road, air and sea including temperature controlled tracking and cold temperature supply chain. CordenPharma also assists customers in purchasing necessary raw materials, excipients and packaging components.

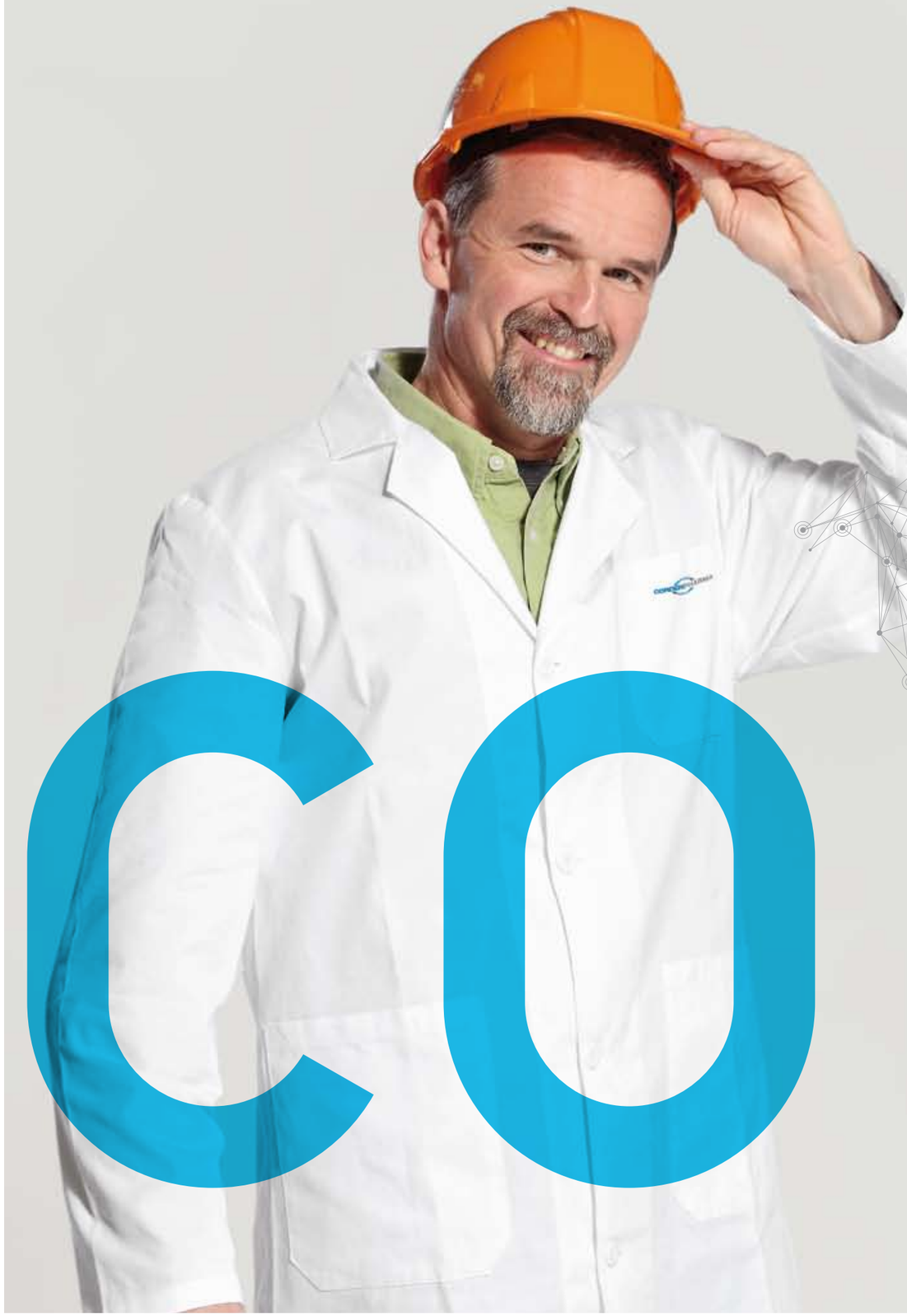

KLOCKNER

OUR FACILITIES

>200 Years
Combined Facility Legacy Experience

Multiple Manufacturing Facilities

Through acquisitions from top pharmaceutical and biotechnology companies, CordenPharma has created a network of multiple cGMP manufacturing facilities across Europe and the US, each with seasoned scientists and over 25 years of production experience using state-of-the-art equipment and technologies with stringent quality systems. Our combined legacy becomes your value when choosing CordenPhama as your preferred outsourcing partner.



CORE

LINKING TOGETHER A LEGACY OF EXPERTISE

CordenPharma's multiple facilities across Europe and the US work together to form an integrated network with a combined facility legacy of over 200 years of experience acquired from top pharmaceutical and biotechnology companies. This combination of expertise, state-of-the-art equipment and stringent quality systems creates strong value in quality, efficiency and price for your outsourcing needs.

FULL–SERVICE CMO FOR A GLOBAL MARKET

We supply a broad range of specialized pharmaceutical products, ingredients and services to a global market in more than 80 countries worldwide. From development to delivery, CordenPharma employs over 650 employees in production serving as a CMO partner to more than 300 active customers globally, including 8 of the top 10 pharmaceutical companies.

FULLY–INSPECTED FACILITIES

Our facilities are fully-inspected by all relevant health agencies including the EMA, FDA and PMDA, as well as audited by numerous customers. We routinely receive >50 audits per year and frequent KPI Assessments from the majority of our customers, with consistent recognition naming CordenPharma as their preferred supplier.

KEY FACILITY CAPACITIES

For APIs, CordenPharma utilizes small-scale R&D labs for multi-gram API development & manufacturing and large-scale API contract manufacturing reactors pools with highly-flexible sizes, including the largest capacity for peptide production and HPLC purification available worldwide. Our API manufacturing sites contain volumes of over 1300 cubic meters for multi-purpose reactions.

For Drug Products, our facilities for formulation and drug product manufacturing span from development of less than 100g to commercial batch sizes.

All our plants are fully equipped with extensive, flexible and state-of-the-art packaging capacities, associated with the most modern tracking and anti-counterfeiting measures.
See our Facility Brochures for more information.

- Flexible Volumes >1300 m^3 of Multi-purpose Reaction Volumes
- Largest Peptide Capacity Worldwide
- Over 650 Employees Working in Production
- 16 Packaging Lines for Primary & Secondary Packaging
- Markets Served >80 Countries Worldwide

- >50 Audits for Agencies & Customers per Year
- Successful Joint Inspection by the FDA & EMA
- Continuous Improvement & Training for Employees
- Code of Ethics & Conduct

SURPASSING STANDARDS

Successfully Inspected
by the FDA, EMA, PMDA, ANVISA

Audited by 8 out of the Top 10 Pharma

CordenPharma experts understand that being a global CMO partner in over 80 countries means a continuous commitment to compliance with worldwide Health Agencies and customers via audits, inspections and a code of ethics. We bring over 200 combined years of acquired facility experience with the highest industry standards to excel in meeting the requirements of compliance for your pharmaceutical product success.

TOP

COMPLIANCE AT CORDENPHARMA

CordenPharma's multiple facilities across Europe and the US have a long track record of successful inspections by all major worldwide health agencies such as the FDA, EMA and PMDA, including joint inspections by the FDA/EMA. CordenPharma conducts over 50 audits / inspections from agencies and customers annually, including audits by 8 of the top 10 pharmaceutical companies.

OUR CULTURE OF CONTINUOUS IMPROVEMENT & TRAINING

We maintain a culture of continuous improvement to optimize and enhance quality systems and ensure operational excellence. This culture extends beyond our facilities to their surrounding communities with a commitment to local environmental and regulatory responsibilities as well.

CordenPharma experts receive on-going training to guarantee customers benefit from the highest levels of compliance. In addition, we actively solicit input and regularly receive KPI Assessments from our customers to understand and track their quality and service expectations.

CODES OF ETHICS & CONDUCT

CordenPharma responsibly conducts business through a Code of Ethics and Compliance which communicates to employees and suppliers the importance their actions and decisions have, in a legal and ethical sense, on maintaining both compliance and trust with customers. The policies and procedures include business ethics and industry compliance best practices from International Codes, as well as employee accountability and assessment. Training on our Code of Ethics and Compliance is regularly conducted.

Successfully Inspected by

FDA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

pmda Japan

ANVISA


SPERLATURA
LOC.215
ESTINTORE

WE FOCUS ON YOU

300
Active Customers Globally

80 Countries Served

Our success is not only based on technologies and capabilities, but on people committed to understanding and taking care of your needs as a customer. With approximately 1600 employees, including over 650 people working in production, CordenPharma experts serve greater than 300 active customers in over 80 countries worldwide, including 8 of the top 10 pharmaceutical companies. As your CMO partner we focus on developing and implementing the solutions you require.

REGULATORY SUPPORT SERVICES

CordenPharma supports contracted customers with a highly-skilled staff of over 100 experts in Quality Assurance, Quality Control, and Regulatory Affairs for both APIs and Drug Products.

ANALYTICAL DEVELOPMENT

For APIs and Drug Products (including drug compounds and excipients for bulk and packaged products) at any development stage and scale of synthesis, CordenPharma provides you with complete cGMP compliant analytical support services such as process and cleaning validation, batch release, analytical method development and validation, characterization, stability studies, impurities, analytical reference standards, technology transfer, scale-up, pharmaceutical writing and regulatory filing support in accordance with ICH guidelines.

VALIDATION

CordenPharma facilities conduct validations of all cGMP relevant systems for both APIs and Drug Products from risk analysis and execution to evaluation and validation reporting of products, manufacturing processes, cleaning, analytical methods, IT-systems, and engineering support for equipment. We assist you in producing product quality reviews and support for renewal of your product approvals.

REGULATORY AFFAIRS

Experienced, on-site regulatory affairs teams ensure your regulatory compliance by preparing and maintaining regulatory documentation such as Drug Master Files (DMFs in USA, Europe, Japan, Canada, etc), CMC quality module documentation in CTD format (suitable for the submission of IND, IMPD, NDA, and MAA dossiers), and EP-Certificates of suitability (CEP). As required we support both approvals of NDAs and MAAs during registration as well as post-approvals through response to questions issued by the authorities.

As new regulatory developments arise for your products, we produce all the documentation necessary to submit files for registration in your selected markets.

FOCUSED PROJECT MANAGEMENT

Our dedicated project management process consists of fully accountable project managers working with multi-disciplinary teams to ensure consistent coordination, communication, tracking and reporting of progress and timelines throughout all project phases. They are your direct interface for defining project objectives and receiving deliverables. All technical risks are identified, evaluated, mitigated and reported on a continuous basis. Updated project plans generated by CordenPharma project managers are tracked vigorously to deliver the highest quality to you within agreed upon timelines.

OPTIMIZED GLOBAL SUPPLY CHAIN

Managing a non-integrated supply chain delivers significant hidden costs linked to complexity management, inventory hold up and transportation costs. CordenPharma and its global network of cGMP facilities work together with you to optimize your global supply chain with integrated supply solutions from the development of APIs to final packaging and commercialization.

Our propriety replenishment model is a service that significantly improves customer cash flow management as well as overall customer service without additional supply chain overhead. During launch and post launch, we maintain close proximity with your market planning functions to ensure continuity of supply, alignment of the supply chain and minimal inventory.


POLYPHEM
START
STOP