

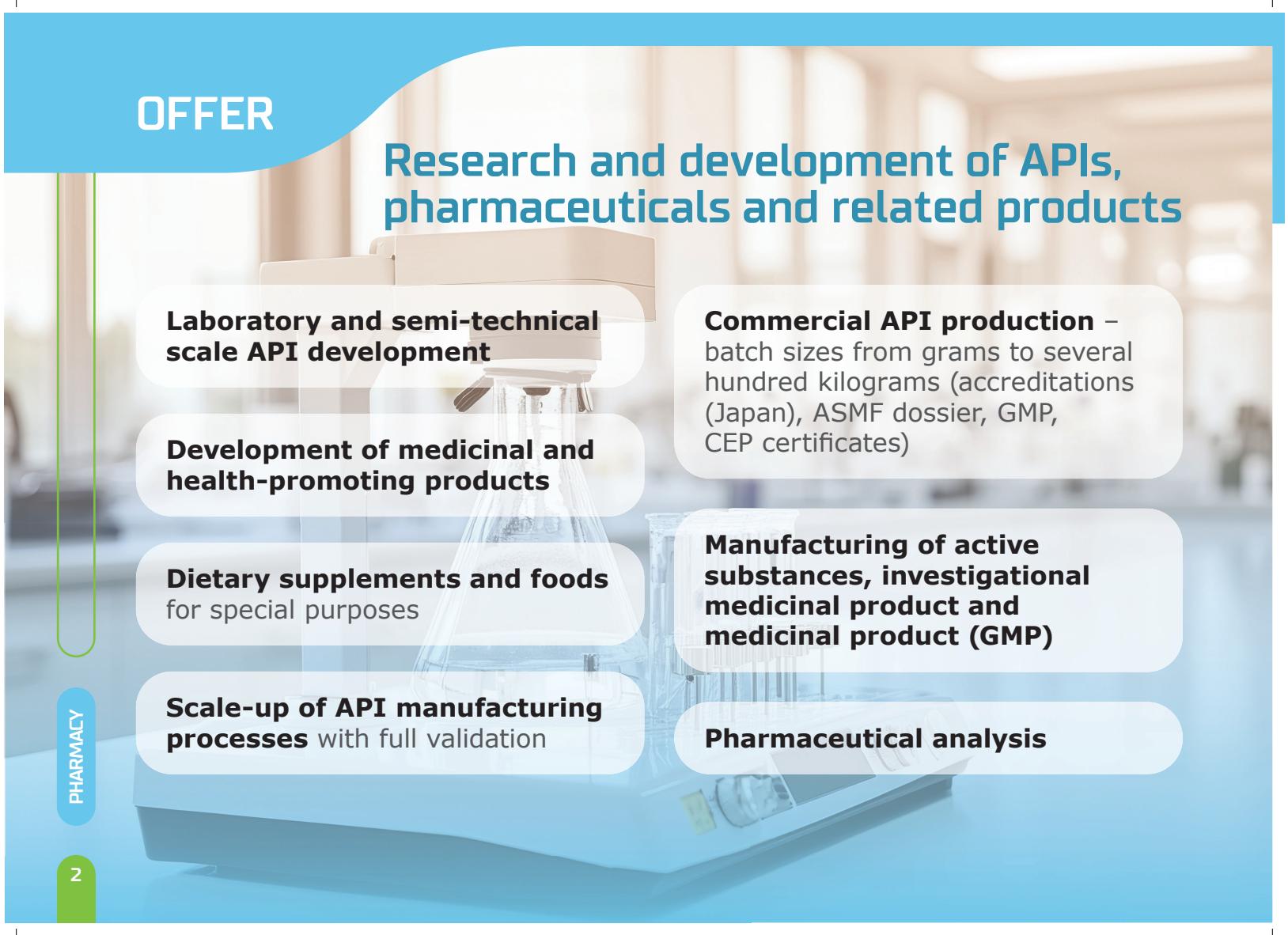
SUSTAINABLE FUTURE STARTS WITH CHEMISTRY

# PHARMACY



## OFFER

# Research and development of APIs, pharmaceuticals and related products



Laboratory and semi-technical scale API development

Development of medicinal and health-promoting products

Dietary supplements and foods for special purposes

Scale-up of API manufacturing processes with full validation

Commercial API production – batch sizes from grams to several hundred kilograms (accreditations (Japan), ASMF dossier, GMP, CEP certificates)

Manufacturing of active substances, investigational medicinal product and medicinal product (GMP)

Pharmaceutical analysis

# LABORATORY AND SEMI-TECHNICAL SCALE API DEVELOPMENT

**development of active substance (API) synthesis and technology pathways,** production of API impurity standards, production of polymorphic forms for API substances

**synthesis planning, laboratory trials, minisynthetic and semi-technical scale** production technology development

**development of innovative small-molecule drug substance technologies** on laboratory and large-scale and research into finding new compounds with biological activity

**scaling** with process validation

**preparation of registration dossiers (ASMF, CTD)**

**carrying out a variety of chemical** (synthesis, catalytic reduction, oxidation, condensation, cyclization) and physicochemical processes (micronisation, crystallisation, large-scale liquid chromatography, fractional distillation) in qualified process equipment and installations

# DEVELOPMENT OF MEDICINAL AND HEALTH-PROMOTING PRODUCTS

**innovative, generic, value-added drug technologies** (combo products, new form / route of administration, reduced dose, modified release)

**innovative personalised forms** for selected audiences (e.g. paediatric, geriatric)

**preparation of IMPD, registration dossiers (CTD) and others**

**development of formulations and manufacturing technologies** for medical devices and dermocosmetic products, including: solid, semi-liquid and liquid formulations (tablets, capsules, syrups, liquids, ointments, creams, ophthalmic drugs)

**post-authorisation changes to the marketing authorisation for medicinal products** (change of API supplier, excipient, packaging, change of batch size, etc.) – full range of cooperation



# FOOD SUPPLEMENTS AND FOODS FOR SPECIAL USES

**proprietary biologically active substances**  
of natural origin, synthetic and biotechnologically modified

**encapsulation systems for bioactive plant compounds**, improved bioavailability of active substances, protection against degradation

**controlled delivery and release technologies, transport systems for active substances**

**personalisation of supplementation**  
in response to the specific needs of different consumer groups

**technologies based on pharmaceutical standards** (quality certification, confirmed composition and purity, standardisation of active substances and production methods)





## SCALE-UP OF API MANUFACTURING PROCESSES WITH FULL VALIDATION

## COMMERCIAL PRODUCTION OF APIs

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**commercial production  
of APIs** (in batches  
from grams to several  
hundred kilograms)

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**contract  
manufacturing of APIs**

# MANUFACTURE OF AN INVESTIGATIONAL MEDICINAL PRODUCT AND A MEDICINAL PRODUCT (GMP)

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**manufacturing the placebo and the investigational medicinal product**

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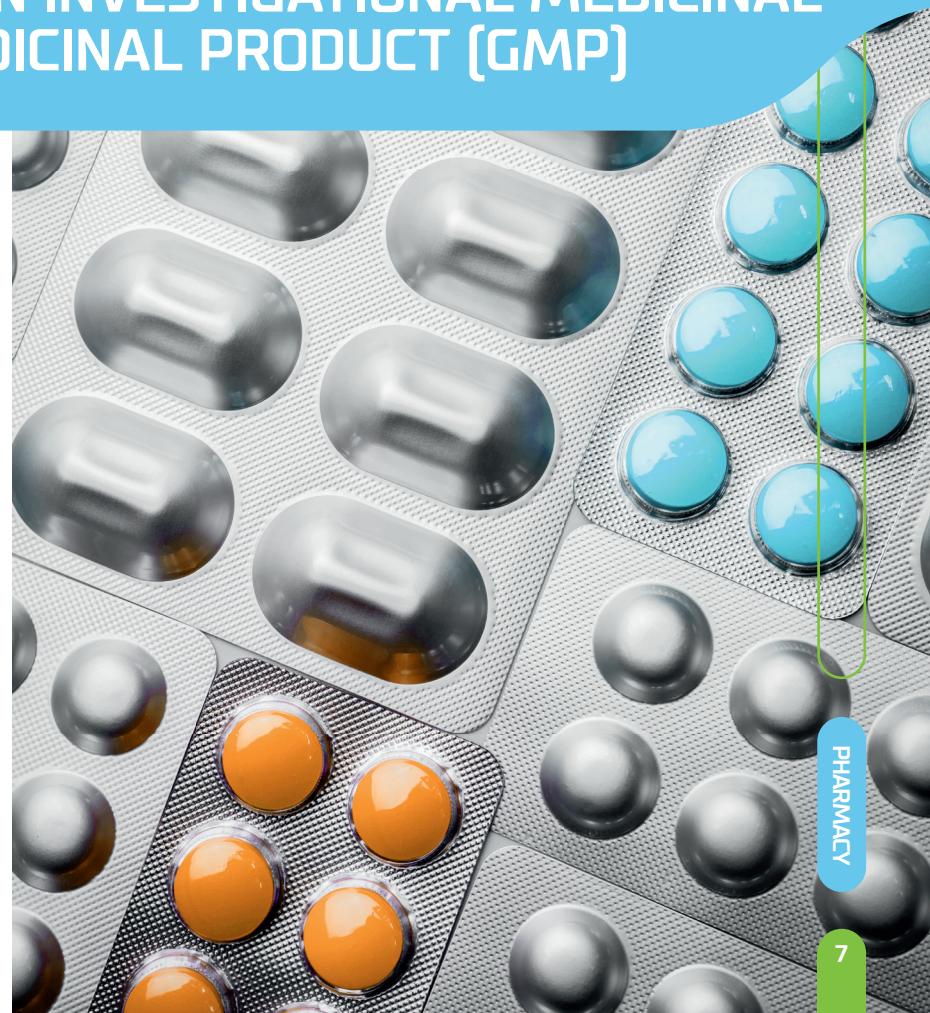
**blinding and repackaging** of the investigational medicinal product, as well as storage and distribution to research centres

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**technological facilities for the manufacture of small batches of drugs** (bioequivalence studies, rare diseases, orphan drugs)

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**responsible entity for the drug Biodribin®** (indicated in hairy cell leukaemia)



# PHARMACEUTICAL ANALYSIS

**safety assurance on the quality** of APIs and finished products

**equivalence and bioavailability studies**  
for medicinal products in the GLP standard

**testing for asepsis, microbiological purity, efficacy of antimicrobial protection, presence of endotoxins**

**development, optimisation, verification and validation** of analytical and microbiological methods

**batch certification for GMP compliance (certificate)** for quality control of medicinal products, active substances, excipients and raw materials

**stability testing of active substances and medicinal products** in qualified climate chambers under long-term conditions

**standardisation of standards for active substances and their impurities**

**transfer of analytical and microbiological methods**

**pharmaceutical availability studies** for various pharmaceutical forms

**impurity profile testing**  
- detection, identification and quantification of impurities in accordance with the requirements of pharmacopoeial monographs (USP, Ph. Eur., FP) and ICH, EMA, FDA

**monitoring of surfaces and air in classrooms**

# OUR API – REGISTRATIONS IN THE WORLD



# VALUES

We work with passion, based on:

Professionalism

Commitment

Reliability

Partnership

# POTENTIAL

## Product and process innovation

from pilot scale to production in our own process halls

## Process scaling

scale-up and scale-down of chemical and biotechnological processes

## Analytical and registration support

for APIs and non-APIs

## Laboratories and equipment

developing research facilities with specialised laboratories and modern equipment

## Development and competence

investment in technology and human resources with more than 170 scientists and specialists for companies investing in innovation

## Inventions and know-how

patented solutions and know-how in the field of modern chemical processes that can be commercialised

## Completion of technological line distributed on the market

from 'concept to product'

## High standards

GMP, GLP, ISO systems in place

## Research platform

implementation of R&D projects

## Cooperation with leaders

cooperation with Polish and foreign business and academic partners



Łukasiewicz

Industrial Chemistry Institute

We create innovations  
that shape a sustainable future.  
Trust our knowledge and experience!

## LET'S MEET!

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