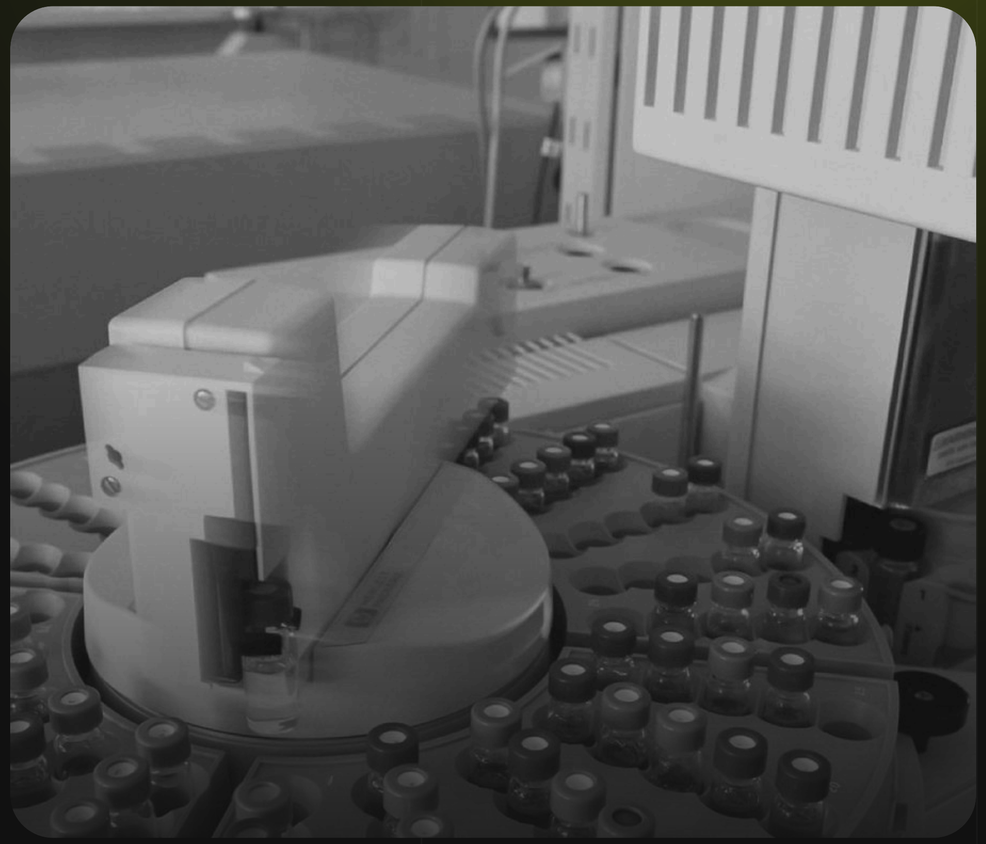
Scientia Ipsa Potentia Est

# Inspection-ready at any moment



International consulting and validation for the pharmaceutical industry. We implement GxP standards, prepare sites for inspections and run pharmacovigilance in the EAEU.

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# About us

SIPE Consulting is an international consulting company in the field of medicinal product and medical device quality. We help build quality systems, optimize business processes and pass inspections with confidence.

2023

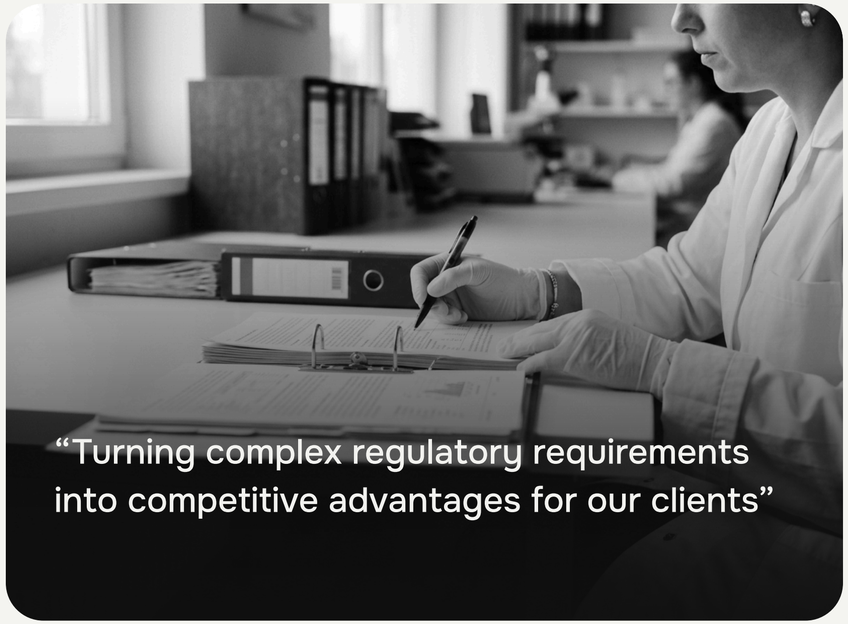
year founded

200+

projects completed in the pharmaceutical industry

ISO 9001:2015

the company's quality management system is certified




01

## Where we work

Russia, the EAEU and the CIS. We work with foreign manufacturers and Big Pharma companies entering the Union market. Offices in Moscow and Karaganda.

02

## How we work

One team covers all six service areas: from data integrity and the quality system to product registration and pharmacovigilance. The first conversation is free and non-binding.

03

## Lifecycle stages

Development, registration, manufacturing, distribution and the post-authorization period — we support the entire product lifecycle.

# Service areas

Six service areas covered by one team. Click an area to go to its description.

**01.** Learn more →

## Data Integrity

Inspectors check not only the product but also its records: who entered the data, when, and whether the change history can be reconstructed.

**02.** Learn more →

## Pharmacovigilance

Without an established PV system, a product's circulation may be suspended. We ensure continuous collection and analysis of safety data.

**03.** Learn more →

## Quality by Design

Quality built into development costs less than quality confirmed by end-of-line testing.

**04.** Learn more →

## GMP and GDP Compliance

Closing inspection observations costs more than preparing for the inspection.

**05.** Learn more →

## Medicinal Product Registration

Dossiers are returned for revision more often because of format and completeness than because of the content of modules and documents.

**06.** Learn more →

## Laboratory Licensing

A laboratory is inspected under the same rules as a manufacturing site.

SECTION 01

# 01

## Data Integrity

1.1 Establishing a QMS in the data integrity field

1.2 Data integrity and digital maturity assessment

1.3 Validation of computerized systems

1.4 Business process analysis for digitalization

1.5 IT infrastructure qualification

1.6 Data integrity specialist outsourcing

To service areas

Data integrity is the ability to prove to an inspector that every GxP record is attributable, legible, contemporaneous, original and accurate (ALCOA+). We build this provability: from company policy to the validated status of every system.

### EXPERIENCE AND EXPERTISE

- **Head of practice** — data integrity expert, international auditor, member of the ISPE EAEU Board of Directors.
- **Contributed to the development** of the industry guideline on data integrity and computerized system validation, harmonized with EEC Board Recommendation No. 25 of 19.09.2023.
- **Validated system classes:** ERP, LIMS, eQMS, eDMS, eBR, laboratory, manufacturing and engineering systems.
- **Regulatory scope:** EAEU, EU (Annex 11) and US (21 CFR Part 11) requirements; GAMP 5 methodology.

Attributable | Legible | Contemporaneous | Original | Accurate | Complete | Consistent | Enduring | Available

ALCOA+ — the criteria inspectors use to evaluate any record

### PUBLICATIONS AND INDUSTRY GUIDANCE

Publications: a series of articles on digitalization and pharmacovigilance in the National Pharmaceutical Journal; industry guideline on data integrity (EAEU).

SERVICES · 01 DATA INTEGRITY

↑ To service areas

# 1.1 Establishing a QMS in the data integrity field

WHAT WE DO

- **Data integrity management policy** — the core document of the GxP data management system
- **Computerized system procedures** — validation per GAMP 5 (risk-based, for all software categories), change and configuration management, security and access, periodic review, audit trail review, record archiving, business continuity
- **IT infrastructure procedures** — incidents and SLAs, IT supplier management, infrastructure qualification, data migration, system retirement
- **Staff training** — on every policy and procedure, with read-and-understood records

Inspectors start with documents: does the company have a data integrity policy and procedures that implement it?

RESULT

A set of policies and SOPs embedded in the company's existing PQS, with staff training.

SERVICES · 01 DATA INTEGRITY

↑ To service areas

# 1.2 Data integrity and digital maturity assessment

WHAT WE DO

- **Computerized system register** — name, controlled process, owners, GAMP category, regulated records
- **Risk assessment of each system** — impact on product quality, patient safety and data integrity; GAMP 5 category
- **Configuration and functionality assessment** of each system against regulatory requirements
- **List of gaps** — configuration, functional and documentation gaps, with remediation recommendations
- **Digital maturity assessment** — which processes still run on paper and spreadsheets, and in what order to move them into systems

Before validating, you need to understand which of the company's systems are GxP-critical and what state they are in.

RESULT

An Excel register of systems, an assessment report and a corrective and preventive action (CAPA) plan.

1 **Inventory**
system register

2 **Risk assessment**
for each system

3 **Assessment**
configuration and functionality

4 **Gaps**
prioritized list

5 **CAPA plan**
timelines and owners

SERVICES · 01 DATA INTEGRITY

↑ To service areas

# 1.3 Validation of computerized systems

WHAT WE DO

- **New system** — implementation and validation from requirements specification (RS) to go-live
- **Existing system** — configuration and validation of a system already in operation to meet regulatory requirements
- **Risk-based approach** — the scope of testing is driven by the GAMP 5 software category and risk assessment
- **Full lifecycle documentation** — validation plan, risk assessment, specifications, IV / FT / UAT protocols, traceability matrix, report
- **Supplier assessment** — leveraging the developer's test results to avoid duplicated work

Validation is confirmation, through objective evidence, that a system is fit for its intended use and meets regulatory requirements (EEC Recommendation No. 25; terminology per GAMP 5, 2nd edition).

RESULT

**A system with confirmed validated status and a dossier ready to present to an inspector.**

RS
**Requirements**
requirements specification

RA
**Risks**
assessment and GAMP category

IV
**Installation**
installation verification

FT
**Functions**
functional testing

UAT
**Acceptance**
user acceptance testing

VR
**Report**
go-live

SERVICES · 01 DATA INTEGRITY

↑ To service areas

# 1.4 Business process analysis for digitalization

WHAT WE DO

- **Process analysis and modeling** — as-is and to-be in BPMN 2.0 notation
- **Building the company's digital ecosystem** — a map of processes and the systems that support them
- **Strategic planning** — IT system implementation priorities by regulatory risk and impact
- **IT system architecture** — building and optimizing integrations between systems
- **Support in selecting and implementing** eQMS, eDMS, eBR and other systems — from requirements to supplier acceptance
- **Validation of implemented systems** — so that digitalization results are inspection-ready from day one

Automating for the sake of automation means getting an expensive electronic copy of the same spreadsheet. Process first, system second.

RESULT

To-be process flowcharts in BPMN 2.0 notation and a technical specification / requirements specification (RS) for developers.

SERVICES · 01 DATA INTEGRITY

↑ To service areas

# 1.5 IT infrastructure qualification

WHAT WE DO

- **Planning** — grouping of infrastructure elements, resources and timelines
- **Risk analysis** — threat assessment for GxP-critical components
- **Technical requirements and specification** — per ISPE GAMP® Good Practice Guide: IT Infrastructure Control and Compliance
- **IQ/OQ testing** — installation qualification and functional testing
- **Reporting and handover to operation** — “qualified” status; the infrastructure is ready for deploying production systems
- **Supporting processes** — change, configuration, backup, security and incident management

A validated system runs on servers, networks and workstations — their suitability must be proven too.

RESULT

A qualified IT infrastructure with a documented status for every GxP component.

SERVICES · 01 DATA INTEGRITY

↑ To service areas

# 1.6 Data integrity specialist outsourcing

WHAT WE DO

- **Change and configuration management** of computerized systems and IT infrastructure
- **Maintaining systems in a validated state** — periodic reviews, requalification
- **SOP development and updates**, staff training
- **IT supplier qualification**
- **Audit and inspection readiness**, support during and after inspections

A team of experts for the price of one specialist: the function is covered; turnover and training are not your concern.

**1–15+**
years of experience across our team

**0**
costs for recruiting and training an employee

RESULT

The data integrity function runs continuously, without depending on a single employee.

SECTION 02

# 02

# Pharmacovigilance

To service areas

Marketing authorization holders (MAHs) are responsible for fulfilling pharmacovigilance tasks and obligations. To this end, MAHs maintain a functioning pharmacovigilance system, including an appropriate and effective quality system for pharmacovigilance.

2.1 Full outsourcing of the pharmacovigilance system in the EAEU

2.2 Periodic safety update reports

2.3 Literature monitoring

2.4 Risk management plan (RMP)

2.5 ICSR management

2.6 Pharmacovigilance outsourcing for veterinary products

EXPERIENCE AND EXPERTISE

- **Qualified person for pharmacovigilance (QPPV)** with experience in building and maintaining PV systems in Russia, the EAEU and Latin America.
- **Regulatory requirements:** EAEU GVP, ICH, EMA, WHO.
- **External audits and inspections** of our PV systems passed: Roszdravnadzor, WHO, CECMED, Kazakhstan MoH.
- **PBRERs and DSURs** accepted by regulators without comments; RMPs for dossiers in the EAEU, the CIS and Latin America.

All work is carried out in our own validated system: case database, literature monitoring, automated submission to the Roszdravnadzor and EudraVigilance gateways, training and document management.

1. **Intake** from any source
2. **Assessment** seriousness and causality
3. **Coding** MedDRA
4. **Generation** ICH E2B(R3)
5. **Submission** to the regulatory authority
6. **Follow-up** acknowledgment

**Deadline for a serious reaction — 15 calendar days · EEC Council Decision No. 87 of 03.11.2016**

SERVICES · 02 PHARMACOVIGILANCE

↑ To service areas

# 2.1 Full outsourcing of the pharmacovigilance system in the EAEU

WHAT WE DO

- **Pharmacovigilance System Master File (PSMF)** — development and keeping it up to date
- **Qualified person for pharmacovigilance** — appointment and notification of the regulator; contact persons in EAEU and CIS countries
- **Standard operating procedures** — a complete set for every process of the system
- **Collection and processing of adverse reactions** — 24/7 call center, assessment, coding, reporting
- **Periodic reports and literature monitoring** — PBRERs, DSURs, RMPs; weekly search by trade name and INN
- **System audit and staff training** — readiness for Roszdravnadzor checks and EAEU inspections

A turnkey pharmacovigilance system: qualified person, documents, processes and deadlines — all in one pair of hands.

**24/7**
intake of adverse reaction reports

**1 QPPV**
qualified person and local contact persons in EAEU and CIS countries

RESULT

**An operating pharmacovigilance system: our procedures are already in place and working — you get a system ready for dossier submission and inspection from day one.**

SERVICES · 02 PHARMACOVIGILANCE

↑ To service areas

# 2.2 Periodic safety update reports

PBRERs and DSURs are a regular assessment of the benefit-risk balance that the regulator expects within fixed deadlines.

WHAT WE DO

- **PBRER (PSUR)** — for authorized products: every 6 months from the international birth date during the first 2 years; annually for the following 2 years; then every 3 years
- **DSUR** — for products in development: annually, structure per Annex 12 to the EAEU GCP Rules
- **Ad hoc submission** — at the request of the competent authority: within 60 calendar days
- **Resubmission** — if the report is rejected by Roszdravnadzor: within 30 working days

**90 days**
to submit a PBRER from the data lock point

**60 days**
to submit a DSUR from the data lock point

**3 weeks**
for our team to prepare a report

RESULT

A report ready for submission: we request the materials, draft the report and agree on revisions — you submit.

SERVICES · 02 PHARMACOVIGILANCE

↑ To service areas

# 2.3 Literature monitoring

Marketing authorization holders should systematically review the scientific medical literature and non-medical sources to identify: — reports of suspected ADRs, — new safety signals, — emerging safety issues.

WHAT WE DO

- **Weekly search** by each trade name and INN
- **Sources** — medical and non-medical periodicals, monographs and conference proceedings, professional society mailings, physician and patient forums, regulator websites, review websites
- **Relevance assessment** — identifying case descriptions and new information on safety and efficacy
- **Handover for processing** — identified cases are entered as ICSRs and follow the standard workflow

**50+**

sources per product

**Weekly**

monitoring cycle and report

RESULT

A weekly report for each product and a demonstrable search history for the inspector.

SERVICES · 02 PHARMACOVIGILANCE

↑ To service areas

2.4

# Risk management plan (RMP)

MAHs are responsible for implementing, operating and evaluating the risk management system (including assessing the effectiveness of risk minimization measures). The RMP describes the product's risk management system: how risks are identified, characterized and minimized; it includes the safety specification, the pharmacovigilance plan, risk minimization measures and evaluation of their effectiveness.

WHAT WE DO

- **For registration** — of biological and original products, and for registration under EAEU rules
- **In case of an emerging safety issue** — at Roszdravnadzor's request (60 working days) or on the holder's own initiative
- **As planned** — upon risk reclassification, a new indication, changes in pharmacovigilance activities or risk minimization measures

**60 working days**

to submit an RMP at Roszdravnadzor's request

**3 weeks**

for our team to develop an RMP

RESULT

An RMP aligned with the registration dossier and PBRER — within 3 weeks of receiving the materials.

SERVICES · 02 PHARMACOVIGILANCE

↑ To service areas

# 2.5 ICSR management

WHAT WE DO

- **Report intake** from all channels: healthcare professionals, patients, literature, partners, call center
- **Report validation** — reporter, patient, product, reaction; invalid reports are entered in the database without reporting
- **Assessment and coding** — seriousness, expectedness, causality, MedDRA
- **Generation and transmission** — ICH E2B(R3) to the Roszdravnadzor AIS and, for some products, to EudraVigilance
- **Data exchange** with the manufacturer and partners, responses to competent authority requests

**15 days**
to submit a serious reaction from “day zero”

**E2B(R3)**
format for transmission to competent authorities

RESULT

Every case is traceable from intake to regulator acknowledgment — in a validated system, not in spreadsheets.

SERVICES · 02 PHARMACOVIGILANCE

↑ To service areas

# 2.6 Pharmacovigilance outsourcing for veterinary products

WHAT WE DO

- **Turnkey pharmacovigilance system** — procedures, responsible persons, intake of inquiries and complaints from veterinarians, animal owners and distributors (para. 301)
- **Collection and assessment of reports** — forms 1 and 2 of Annex 25: causality and frequency of reactions (paras. 299–302)
- **Expedited reports** — serious and unexpected reactions: form 3, within 10 working days; followed by a report on measures taken (paras. 303–304)
- **Periodic safety and efficacy report** — prepared for marketing authorization confirmation (Annex 13)
- **Archive and interaction with the regulator** — data kept for the full authorization period plus 5 years (para. 306); responses to competent authority requests (Rosselkhoznadzor in Russia)

**10 working days**

for an expedited adverse reaction report (para. 303)

**Decision No. 1**

of the EEC Council of 21.01.2022 — Rules for the circulation of veterinary medicinal products

RESULT

An operating pharmacovigilance system: our team runs the processes — you are ready for marketing authorization confirmation and inspection by the competent authority.

SECTION 03

# 03

# Quality by Design

To service areas

Quality by Design is a science-based approach to developing a product and bringing it to market: quality is built in from the early stages of development, reducing costs in both development and commercial manufacturing.

PUBLICATIONS AND INDUSTRY GUIDANCE

A series of articles “QbD (Quality by Design)” in the National Pharmaceutical Journal: quality strategy from the development stage · quality target product profile · critical quality attributes (CQA).

QbD implementation projects take one to three years depending on the complexity of the product and process

WHAT WE DO

- **QbD implementation** — at the client’s site: analysis of organizational structure, policies, standards and procedures, team training
- **New product pathway** — support from concept to the first commercial batches
- **Retrospective QbD** — as part of registration dossier variations for existing products
- **Continued process verification** — moving from periodic revalidation to monitoring throughout the lifecycle

1 **QTPP**
quality target product profile

2 **CQA**
critical quality attributes

3 **CPP**
critical process parameters

4 **Design Space**
design space

5 **Control Strategy**
control strategy

SECTION 04

# 04

## GMP and GDP Compliance

4.1 Inspection preparation and support

4.2 Pharmaceutical quality system development

4.3 Design qualification (DQ)

4.4 Sterilizing filtration validation

4.5 Third-party audits

4.6 Quality assurance outsourcing

To service areas

A functioning pharmaceutical quality system is a GMP requirement under ICH Q10, EEC Council Decision No. 77, FDA and EMA. We build it, audit it, support it during inspections and run it on an outsourced basis.

EXPERIENCE AND EXPERTISE

- **Industrial pharmacy experts** with more than 14 years of experience in pharmaceutical manufacturing, including radiopharmaceuticals and aseptic manufacturing.
- **Management of manufacturing** of biotech products, biomedical cell products and medical devices; site development and product export.
- **Audits and inspections** — comprehensive audits for Russian and international regulators, preparation for Minpromtorg licensing inspections.
- **Design** — design qualification (DQ) of facilities for radiopharmaceuticals, APIs, sterile and solid dosage forms.

SERVICES · 04 GMP AND GDP COMPLIANCE

↑ To service areas

# 4.1 Inspection preparation and support

WHAT WE DO

- **GAP analysis** — PQS documents and the site against EAEU / EU GMP and licensing requirements
- **Mock inspection** — following a real inspection scenario, with observations and a plan to close them
- **Staff preparation** — how to answer the inspector and which records to present
- **Presence at the inspection** — handling inspector requests, preparing documents as the inspection proceeds
- **Remediation** — CAPA until observations are closed, and the response to the regulator

We support licensed sites during inspections: we take over preparation and interaction with inspectors so you can stay focused on production.

RESULT

**The site passes inspection with a minimum of observations, and those raised are closed on time.**

1 **Assessment**
gap against requirements

2 **Preparation**
documents and staff

3 **Inspection**
on-site support

4 **CAPA**
closing observations

SERVICES · 04 GMP AND GDP COMPLIANCE

↑ To service areas

# 4.2 Pharmaceutical quality system development

WHAT WE DO

- **Building a PQS from scratch** — for new companies and sites
- **Support in shaping the PQS** — for existing companies
- **Documentation GAP analysis** — against GxP requirements
- **Document development** — company policy, corporate standards, SOPs, process instructions, methods and forms for LIMS integration
- **Creating or updating a single PQS document** — when a targeted result is needed

The PQS is the system for managing a company with regard to quality at every stage of the product lifecycle.

**ICH Q10**

pharmaceutical quality system model

**Decision No. 77**

EAEU GMP Rules

RESULT

A structured, documented PQS that can be presented to an inspector in any jurisdiction.

SERVICES · 04 GMP AND GDP COMPLIANCE

↑ To service areas

# 4.3 Design qualification (DQ)

WHAT WE DO

- **User requirements specification (URS)** — the basis for the design and subsequent qualification stages
- **Design qualification (DQ)** — compliance of design solutions with GMP: flows, cleanliness classes, utilities
- **Facilities** — cleanrooms, HVAC, PW / WFI / clean steam / compressed gas systems, warehouses and cold rooms, process and laboratory equipment
- **High-hazard manufacturing** — radiopharmaceuticals, toxic, hormonal and cytotoxic products, biotech products, blood products
- **Subsequent stages** — support for FAT / SAT, IQ / OQ / PQ

A mistake at the design stage costs the most: the premises are already built and the equipment already purchased.

RESULT

**A design that passes expert review and inspection without rework.**

URS **Requirements**

DQ **Design**

FAT/SAT **Acceptance**

IQ **Installation**

OQ **Operation**

PQ **Performance**

SERVICES · 04 GMP AND GDP COMPLIANCE

↑ To service areas

# 4.4 Sterilizing filtration validation

WHAT WE DO

- **Validation strategy** — per Annexes 1 and 15 of the EAEU / EU GMP Rules
- **Microbial retention testing** — bacterial challenge test with the product on the selected filter
- **Compatibility and integrity** — filter-product compatibility, adsorption, pre- and post-use integrity tests
- **Extractables and leachables (E&L)** — extractables study on the filter and leachables in the product, toxicological risk assessment
- **Process parameters** — differential pressure, filtration time, volume, temperature; justification of limits
- **Documentation** — validation protocols and reports, inclusion in the validation master plan and registration dossier

For sterile products that cannot be terminally sterilized, filtration is the last barrier — and its reliability must be proven.

RESULT

Proven sterilizing capability of the filter for the specific product and process.

SERVICES · 04 GMP AND GDP COMPLIANCE

↑ To service areas

# 4.5 Third-party audits

WHAT WE DO

- **Manufacturers of APIs and finished products** — sterile and non-sterile (GMP)
- **Manufacturers of excipients and packaging materials** (GMP)
- **Contract testing laboratories and service providers** (GMP)
- **Distributors** (GDP) and clinical research sites (GCP)

An independent, objective assessment of a site's compliance with EAEU and EU requirements — by experts with hands-on experience at certified manufacturing sites.

**1–3 days**
on-site audit

**≤ 14 days**
full report and proposed CAPA plan

RESULT

A report you can rely on when qualifying a supplier or preparing for your own inspection.

SERVICES · 04 GMP AND GDP COMPLIANCE

↑ To service areas

4.6

# Quality assurance outsourcing

Not every company needs a fully staffed QA department. We take over its functions — fully or partially — under a contract and a technical agreement.

WHAT WE DO

- **PQS documentation** — SOPs, master documents, document flow and records
- **Deviations, CAPA and changes** — investigation, risk assessment, implementation control
- **Complaints and product recalls** — investigation, communication with the competent authority
- **Product quality reviews** and management review of the PQS
- **Self-inspections and audits** — suppliers, contract sites, quality agreements
- **Staff training** and inspection preparation
- **Technology transfer** — support under EEC Guideline No. 11: from the transfer agreement to the first commercial batches and release into circulation

## Decision No. 77

EAEU GMP Rules, Chapter 7 — outsourcing under a written agreement

## Recommendation No. 11

of the EEC Board — Guideline on technology transfer

RESULT

A working quality assurance system without expanding headcount — a team of experts for the price of one specialist.

SECTION 05

# 05

# Medicinal Product Registration

5.1 Registration of medicinal products
5.2 Variations to the registration dossier
5.3 Registration of veterinary medicinal products
5.4 SmPC and package leaflet development
5.5 Package leaflet user testing

To service areas

A registration dossier is not only data but also form: module structure, XML submission, responses to regulator queries during completeness checks and expert review. We manage the dossier from the first module to the marketing authorization and handle variations after registration.

CAPABILITIES

- **Full dossier under EAEU rules** — Modules 1–5, SmPC and package leaflet, XML coding, application submission and status tracking.
- **Individual modules** — when part of the dossier is ready and part needs to be written or brought into compliance.
- **Audit of a completed dossier** — a tracker for each section with comments and recommendations, 14 working days.
- **Expert review support** — providing samples for testing, qualified responses to regulatory queries.
- **Variations** — for Russian and foreign holders, including bringing dossiers into line with EAEU requirements.

SERVICES · 05 MEDICINAL PRODUCT REGISTRATION

↑ To service areas

# 5.1 Registration of medicinal products

WHAT WE DO

- **Modules 1 and 3** — administrative and quality parts: preparation, compilation, agreement
- **Modules 2.4–2.7, 4 and 5** — nonclinical and clinical overviews and reports (including section 1.8)
- **SmPC and package leaflet** — development and user testing
- **XML coding and submission** — a single valid file via the GRLS / Regmed personal accounts
- **Turnkey expert review** — transfer of samples for testing, well-founded responses to queries

A full registration dossier under EAEU rules — from the first module to application submission.

RESULT

Each module separately or a turnkey dossier — up to the marketing authorization. After registration — variations, see slide 28.

1 **Assessment**
completeness of available data

2 **Modules**
step-by-step development

3 **Compilation**
complete dossier

4 **Submission**
XML and application

5 **Expert review**
samples and queries

SERVICES · 05 MEDICINAL PRODUCT REGISTRATION

↑ To service areas

# 5.2 Variations to the registration dossier

WHAT WE DO

- **Change assessment** — type of variation under the EAEU Registration and Expert Review Rules: notification or expert review; list of documents
- **Updated dossier sections** — Modules 1–5, SmPC, package leaflet, packaging mock-ups
- **XML coding and submission** — via the GRLS / Regmed personal accounts
- **Samples for expert review** — preparing and transferring samples to the expert organization when the variation requires laboratory quality testing
- **Expert review support** — responses to competent authority queries until the variation is approved

Any change to a product — manufacturing, methods, packaging, SmPC — must be entered into the registration dossier. We handle it end to end.

RESULT

**Variations entered into the registration dossier end to end, including samples for expert review.**

1 **Assessment**
type of variation

2 **Documents**
updated sections

3 **Submission**
XML and application

4 **Samples**
for expert review

5 **Expert review**
responses to queries

SERVICES · 05 MEDICINAL PRODUCT REGISTRATION

↑ To service areas

# 5.3 Registration of veterinary medicinal products

WHAT WE DO

- **Regulatory pathway assessment** — national or EAEU procedure, dossier requirements for the specific type of product
- **Registration dossier** — administrative, quality, nonclinical and clinical parts
- **Instructions for use and labeling** — per veterinary product requirements
- **Submission and support of the registration application** — responses to regulator queries on dossier completeness and content
- **Variations** — assessing the changes and documents required for the application; planning the timeline for amending the marketing authorization
- **Release into circulation** — advice on requirements for releasing the first batches after registration: documents, labeling, conformity confirmation procedure

Veterinary products are registered under separate EAEU rules and national procedures — with their own dossier and expert review requirements.

RESULT

A dossier that meets the requirements for veterinary products, with support up to the marketing authorization and release into circulation.

SERVICES · 05 MEDICINAL PRODUCT REGISTRATION

↑ To service areas

# 5.4 SmPC and package leaflet development

WHAT WE DO

- **SmPC** — following the EAEU structure and requirements for the summary of product characteristics, based on dossier data
- **Package leaflet** — based on the SmPC, in patient-friendly language; layout and readability
- **Consistency** — SmPC, package leaflet and labeling do not contradict each other or the dossier
- **Alignment with the reference product** — for generics
- **Updates** — for safety changes, new indications, variations

The summary of product characteristics and the package leaflet are read by the physician, the patient and the expert — each in their own way.

RESULT

A set of SmPC and package leaflet ready for submission and user testing.

SERVICES · 05 MEDICINAL PRODUCT REGISTRATION

↑ To service areas

# 5.5 Package leaflet user testing

WHAT WE DO

- **Package leaflet proofreading** — checking for punctuation and grammar errors
- **Respondent group selection** — taking into account the product and its target audience
- **Protocol and questionnaire** — documenting the testing methodology
- **Pilot and main stages** — questionnaire validation, conducting the survey, recording results
- **Report** — test results and recommendations for improving the package leaflet, if any arise from the testing

**600+**
user testing packages submitted

**4+ years**
of our expert's experience in user testing

**Database**
of respondents across therapeutic areas; extensive experience with user testing queries and responses to them

A package leaflet is considered fit for purpose if patients can find the information they need and understand it correctly. This is tested on respondents.

RESULT

Protocol, report and summary of the user testing for inclusion in the registration dossier.

1. **Respondents** group selection
2. **Protocol** and questionnaire
3. **Pilot** questionnaire validation
4. **Main stage** survey
5. **Report** and recommendations

SECTION 06

# 06

# Laboratory Licensing

To service areas

A laboratory goes through licensing and inspection under the same rules as a manufacturing site: premises, equipment, personnel, documentation and electronic records.

WHAT WE DO

- **Site readiness assessment** — gaps in premises, equipment and procedures
- **Document preparation** — a complete set for the license application
- **Inspection support** — presence during Minpromtorg inspections and remediation of findings
- **Staff training** — GMP and licensing requirements as applied to the laboratory
- **Electronic document management** — implementation of a validated document management system per GMP and Decision No. 77

Preparing the site and staff for inspection, with our presence at every stage

1. **Assessment** — site gaps
2. **Dossier** — document package
3. **Application** — to the authority
4. **Inspection** — on site
5. **License** — closing findings

# EAEU Representation

We represent foreign pharmaceutical manufacturers in the Eurasian Economic Union. Our focus is companies from India and China entering the markets of Russia, Kazakhstan, Belarus, Armenia and Kyrgyzstan.




**5**

EAEU member states under a common regulatory framework

**India · China**

focus regions for the manufacturers we represent

**1 contact**

for registration, pharmacovigilance and GMP matters

01

### What we take on

Local representation of the marketing authorization holder: communication with regulators, registration and variations under EAEU rules, a local QPPV and contact persons in each country.

02

### For whom

Manufacturers from India, China and other countries that are entering the EAEU market or already supply it and need a reliable partner on the ground.

03

### How we work

One contract covers the whole scope: from dossier adaptation and preparation for GMP inspections by EAEU inspectorates to pharmacovigilance after registration.

# Free consultation

Tell us what stage your product or site is at, and we will identify which tasks need to be addressed first and on what timeline.

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1

## Conversation

in person or online



2

## Express assessment

where you are now

The first conversation is non-binding and free of charge

3

## Work plan

priorities, timelines, cost

Scan to open our website with service descriptions and a request form.