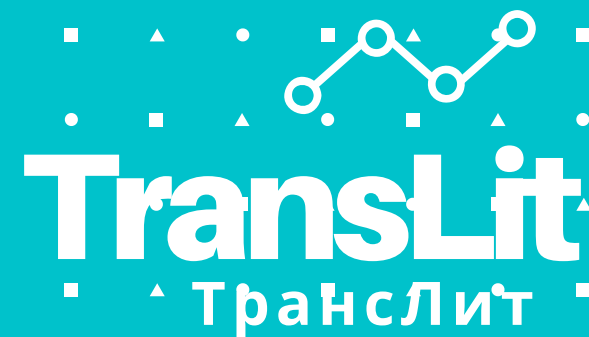


TransLit

2021





Services for Pharma

Translations:

- only for pharmaceutical companies
- experienced staff in this sphere (more than 10 years)
- general european languages and others

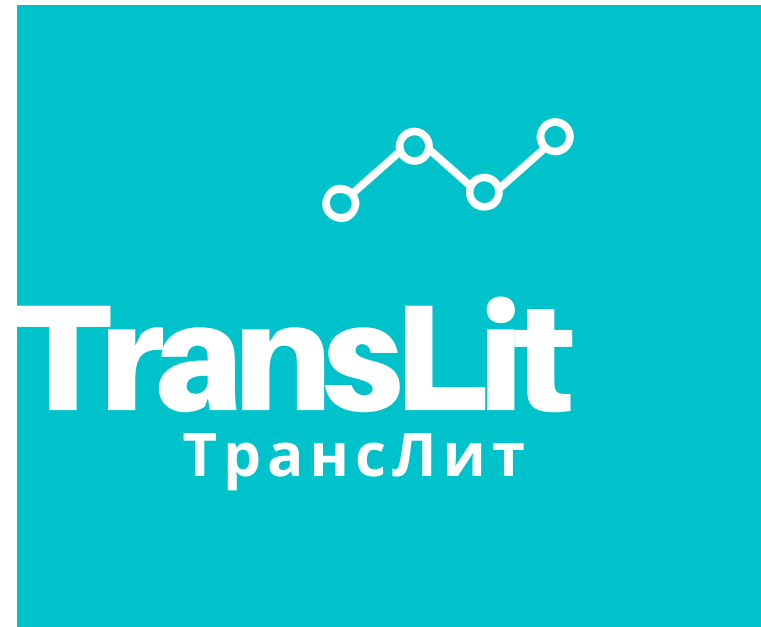
Regulatory affairs:

- finish dosage forms human and vet approvals&variations
- GMP inspection assistance
- API circulations
- nutritionals and medical devices

Pharmacovigilance:

- audits
- full package of documentation
- QPPV in Russia and EAEU

since 2009 on the market



Our activity in figures

2020

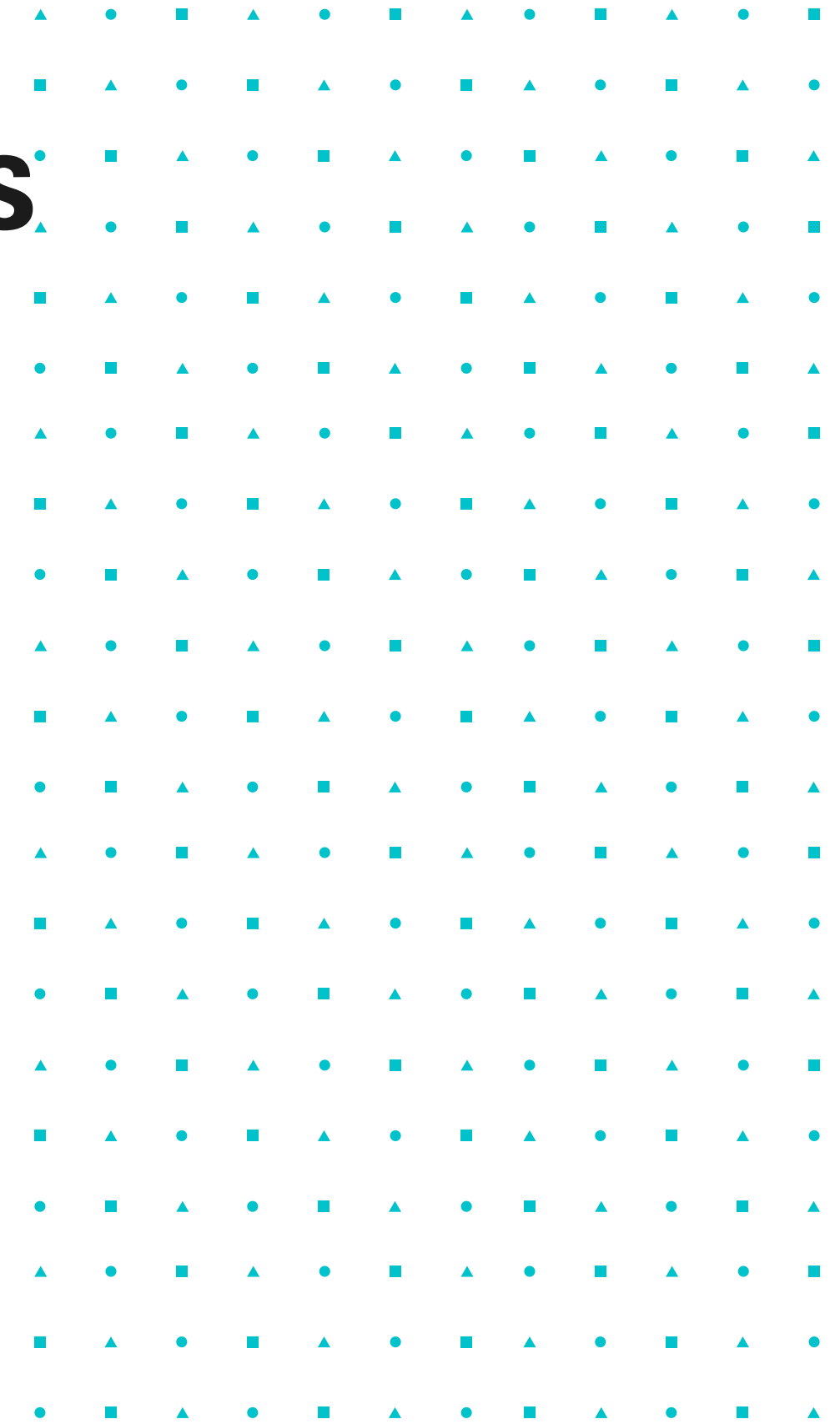
Regulatory affairs 36%

Inspection GMP RF 4%

Translations 55%

Pharmacovigilance 4%

Price registration 1%





Nutritionals

more than 30 products were investigated for launch to the russian and EAEU markets. Some projects are at the consultation stage now: portfolio checking for future launches.

We have all required tools to approve products in EAEU.

Medicinal products

We can act as a local representative of foreign companies providing services:

- portfolio support (necessary variations etc)
- new product launch strategy
- marketing authorization for new products
- pharmacovigilance
- constant consulting
- samples importation
- serialization
- other services

Active Pharmaceutical Ingredients

We have registered more than 20 products and we support it in the future regulatory lifecycle.

We are at your disposal for local clients services

Price registration

We are registering prices for essential and vital products since 2015

Regulatory affairs experience



Translation volume

Our facilities are enable for 10 000 pages/month.

We translate all documentation used by pharmaceutical companies: from COA to clinical reports, from validation data to pharmaceutical development. So documents of eCTD+marketing +legal documentation

Our advantages

We have a deep experience in Pharma sphere as we are specialized in this sphere and working also as pharmaceutical staff for local and foreign companies. We understand that each Companies will require particular approach.

Our clients

Russian and foreign pharmaceutical and veterinary Companies

Speed of preparation

We use the fastest way to documentation preparation as we know how important is to make the fasterst product launch

Translations experience



Documents of Quality Management and PV systems

We are preparing all needed documents for setting up of PV system (necessary SPOs, instructions and all other required documents) and supporting this system further.

We also teaching staff to operate in working PV system

Documentation in figures

PSUR 10

DSUR 15

RMP 4

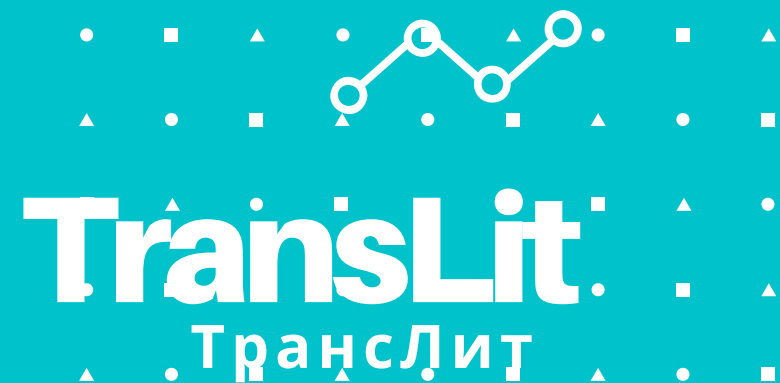
PV Master file 2

PV SOP 83

Audits

We are experienced in PV system audits for local (Russian) companies

PV experience

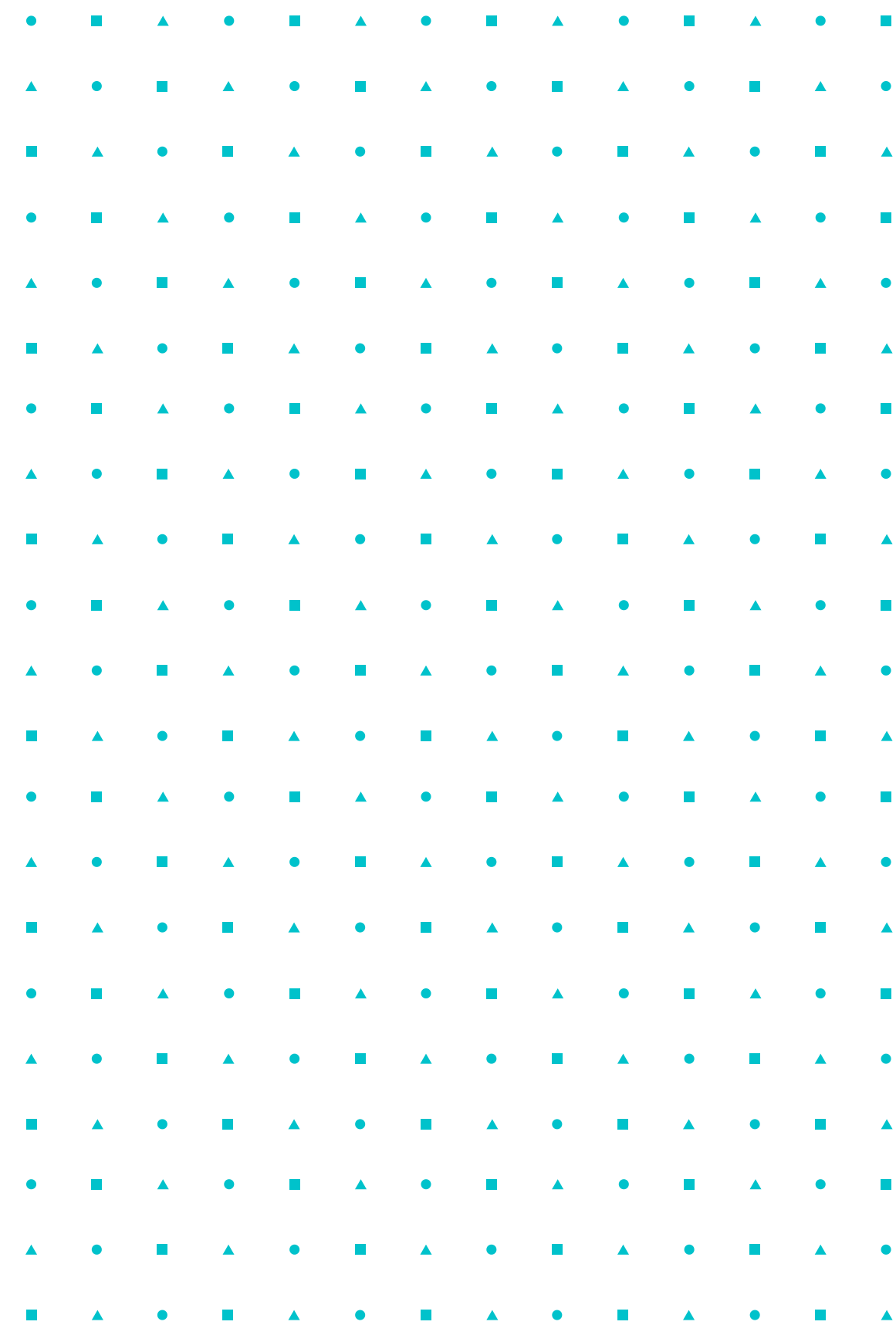


Some words from our CEO



Pharmaceutical companies can be sure about the quality and efficacy of our work and do not worry about projects' features. Our methods of work are based on win-win principles.

Irina Ulianova



**Thank you for
your readiness to
the co-operation!**

info@oootranslit.ru