












Project and GMP consulting references

Year/Years of development of projects	Customer	Name and description of the project	Location of the object
April-May 2015	R-Pharm JSC	Concept-project of multifunctional laboratory building	Yaroslavl, Russia
April-May 2015	non-public customer	Development of planning concepts on a new production	Africa
June - August, 2015	Akrikhin JSC	Concept-project on creation of areas for primary and secondary packing of solid drug forms	Starya Kupavna, Russia
May - August, 2015	R-Pharm JSC	Development of documentation at the stage of "Detailed Design" on "Troika" project, sections on HVAC. Qualification.	Yaroslavl, Russia
August - November, 2015		Concept-project for Kaluga plant expansion. FlexPen assembly.	Kaluga, Russia
September - December, 2015	Akrikhin JSC	Concept-project for arrangement of laundries on the existing production	Starya Kupavna, Russia
November - December, 2015		Development of Site master plan and TIC	Russia
November - December, 2015	Pharmaceutical Engineering Institute	Concept-project of new production and training building for solid dosage forms	Moscow, Russia
May - July 2016	Non-public customer	Concept-project of blood substitutes pharmaceutical facility with product warehouse	Astana, Kazakhstan

June September 2016	-		Design and working documentation for sampling premises on the existing production	Kaluga, Russia
July September 2016	-		Development of planning concepts for a new production building of liquid formulations	Moscow, Russia
June 2016		Non-public customer	Development of concept solutions, section "Process solutions" of the stage "Approved project part" for undergoing expert review of new production of antineoplastic agent belonging to orphan products with OEB 5 protection level	Yaroslavl, Russia
July 2016		Non-public customer	Development of section "Process solutions" of the stage Approved project part for undergoing expert review of new production of medical products - coronary stents including those which are coated with preparation of OEB 5 protection level	Moscow, Russia
March 2016		Signatum (Pascal Medical)	Expertise of the project of production of polymeric three-component disposable syringes with mounted needle	Dubna, Russia
September 2016		Signatum (Pascal Medical)	Development of section "Process solutions" of the stage "Approved project part" of production of polymeric three-component disposable syringes with mounted needle	Dubna, Russia
March 2017		 R.G.C.C Greece Ltd.	Development of planning concepts for a new production building of antitumor sterile and unsterile liquid formulations	Greece
March 2017		Signatum (Pascal Medical)	Development of section "Process solutions" of the detailed design project of production of polymeric three-component disposable syringes with mounted needle, including quality control laboratory	Dubna, Russia

April 2017	Signatum (Pascal Medical)	Development of concept project, section "Process solutions" of the production of medical devices, infusion and transfusion systems	Dubna, Russia
September 2017	Signatum (Pascal Medical)	Development of project, section "Process solutions" of the stage "Approved project part" of the production of medical devices, infusion and transfusion systems	Dubna, Russia
October 2017	 MedInTech	Development of concept solutions, section "Process solutions" and of the stage "Approved project part" for undergoing expert review of new production of disposable syringes of third generation, including quality control laboratory	Astrakhan, Russia
October 2017	 MedInTech	Development URS for process equipment, support the client in communication with vendors and contractors and purchasing of the equipment	Astrakhan, Russia
March 2015 – present	 Novo Nordisk	<p>Support in the field of quality assurance and implementation of qualification and validation activities (development of validation plans, equipment and systems risks analysis, and URS preparation, forwarding during FAT/SAT tests, development of qualification protocols and reports DQ, IQ, OQ, PQ, including tests, SOP writing)</p> <p>Writing protocols for following directions (work packages):</p> <ul style="list-style-type: none"> - equipment, systems and processes for provision of production aseptic conditions; - equipment, systems and processes for washing and sterilization; - equipment, systems and processes for provision with "clean" means; - systems BMS (automated building management system) and FMS (automated critical parameters monitoring system) <p>Development of process procedures for 6 preparations of the Company-Customer</p> <p>Support in the field of project management and planning</p>	Kaluga, Russia

<p>March- December 2015</p>		<p>Support during the implementation of project for location of contract production of antidiabetic agent within the area of existing enterprise in North Africa, particularly, developing «User requirements specifications» for process equipment and systems Development of validation plans, development of qualification protocols in the following directions (work packages):</p> <ul style="list-style-type: none"> • equipment, systems and processes for provision of production aseptic conditions; • equipment, systems and processes for washing and sterilization; • equipment, systems and processes for solutions preparation; 	<p>North Africa</p>
<p>December 2015</p>		<p>Examination of conceptual design of microbiological facility for Kurgan JSC "Sintez", (DR)</p>	<p>Kurgan, Russia</p>
<p>January 2016 - present</p>		<p>Support during the implementation of project for location of contract production of antidiabetic agent within the area of existing enterprise, particularly, service rendering in the field of quality assurance and qualification/validation measures (development of validation plans, development of qualification protocols and reports IQ, OQ, PQ, including tests, SOP writing) in the following directions (work packages):</p> <ul style="list-style-type: none"> • equipment, systems and processes for provision of production aseptic conditions; • equipment, systems and processes for washing and sterilization; • equipment, systems and processes for solutions preparation; • equipment, systems and processes for aseptic filling 	<p>Kaluga, Russia</p>

November 2017-January 2018	Non-public customer	Development of concept project for a new production and packaging area of sterile liquid formulations	Altai, Russia
November 2017-January 2018	Non-public customer	Conceptual project of Microbiological laboratory and offices on the existing production site	Yaroslavl, Russia