Warsaw, 27 October 2023

Inquiry NO. NUSI/48/PR31403/2023
being conducted as a market assessment study

In connection with the implementation of the project titled *"Development of a universal fast-response platform, based on RNA technology, ensuring the national drug and epidemiological safety*", co-funded from the state budget by the Medical Research Agency, Warszawskie Zakłady Farmaceutyczne Polfa S.A., you are kindly requested to submit a bid for **evaluation, coordination of conceptual and design modifications and confirmation of completeness of the design documents** constituting the Conceptual & Basic Design as well as the Quality Documentation and the Validation Documentation.

I. NAME AND ADDRESS OF THE CUSTOMER

Warszawskie Zakłady Farmaceutyczne Polfa S.A.
ul. Karolkowa 22/24
01-207 Warszawa

II. CONTRACT AWARD PROCEDURE

1. This contract is not subject to the provisions of the Public Procurement Law of 11 September 2019 (consolidated text: Journal of Laws of 2019, item 2019)
2. The procedure is being conducted as an intentional and cost-efficient market assessment study while respecting the following rules:
1) to achieve the best possible outcomes using the allocated resources;
2) to choose the best possible means and methods to meet the pre-defined objectives;
3) to ensure transparency, fair competition and equal treatment of contractors.

III. DESCRIPTION OF THE SUBJECT OF THE INQUIRY

III.1. The subject of the Inquiry is *the provision of evaluation services, coordination of conceptual and design changes and confirmation of completeness of the design documents constituting the Conceptual Design, The Basic Design as well as the Quality Documentation and the Validation Documentation.*

III.2. Description of the project:

Design and release for use of a new research and production site located in Starogard Gdański at 19 Pelplińska Street on the premises of Zakłady Farmaceutyczne Polpharma SA. - Parenteral Dosage Forms Production Facility.
A description of the site is provided in Appendix 4 hereto. A floor plan of the site, showing the location of the individual areas, is attached in Appendix 5 hereto (this floor plan should be treated as illustrative - it may change during the design process).

Due to the need to design and release for use the described site, the scope of work will include design and release for use of a GMP manufacturing area, including detailed design specifications for the consecutive operations involved in the manufacture of clinical trial batches and small-sized commercial batches, taking into account products characteristics as well as all process-related activities (Pilot Plant, dosage forms: sterile solutions for injections in vials, sterile solutions for injections, PFS, Cartridge – PFS).

The purpose of the project is to obtain a manufacturing authorization and GMP certificate for investigational medicinal products and for the manufacture of small-sized batches of commercial products belonging to the group of antisense oligonucleotides (siRNA), analogs of human oligopeptides, small molecules (for detailed characteristics of reference products and technology, see Appendix 3 hereto).

The required supply utilities available on site:
– electric power
– water for injections (WFI)
– clean steam (in-house generator)
- clean/process gases (nitrogen, compressed air)
– hot water
– hot water – HVAC
- chilled water – HVAC
– condensate

The project covers the following systems:
- HVAC (AHU, Chillers, UDAF, ventilation ducts)
– toxic wastewater disposal system
– sewage disposal system
– RMS
– BMS
– PMS
– AC
– CCTV
– UPS
– PLC
– electrical wiring (building-wide)

Processing and auxiliary equipment included in the project:
- insulator for weighing
- UDAF – weighing room
- solution preparation system – (SUS)
- filtration unit
– autoclave
– VHP chamber
– automatic parts washer
– filling line (vials/PFS/cartridges)
– balances;
- isolated transport system
- decontamination shower (MS)

- mobile UDAF
- serialization module (optional)

Toxic substances of categories up to and including OEB5 will be handled in the manufacturing area. It may be required that APIs/finished products be kept under reduced temperature (for detailed specifications, see Appendix 3).

The manufacturing plant should meet the requirements of:
- EU-GMP, in particular the requirements of Annex 1 'Manufacture of Sterile Medicinal Products' (the draft of the new Annex 1 should also be taken into account);
- US-FDA;
- CA;
- EAU.

The quality, validation documentation should be developed and evaluated based on regulatory acts relating to Good Manufacturing Practices as well as any other standards and regulatory acts applicable to the relevant markets.

III.3. Scope of the Inquiry:

- Punctual (as per agreed schedule) assessment of submitted design specifications, including in particular the critical aspects in terms of GMP (CDEs, CAs), which might be relevant to the critical quality attributes of the finished product (CQA) or critical process parameters (CPP), e.g. general layout, HVAC layouts, P&ID HVAC, classification layouts, materials/staff/product/waste flow layouts, process flow, process description, equipment layout, utilities layouts, detailed design criteria – HVAC, etc. (for a full list of documents included in the design specifications at the conceptual and baseline design stage, see **Appendix 7** hereto);

- providing assessments, evaluation and active participation in the development of qualification / validation and quality documents, i.e. DR/DQ (GMP Review, URS Review), Containment Strategy, SIA, Validation Master Plan, Risk Analysis, HAZOP, CCS etc. (for a full list of quality / validation documents to be developed / provided with additional information based on reviewed and approved design specifications at the baseline design stage, see **Appendix 6** hereto);

- Participation in regular project meetings on site / TC (as necessary and as agreed) organized as part of meetings with designer, general contractor, subcontractors and members of the Design Team or PQC (Project Quality Coordinator)

- Punctual (as per agreed schedule) evaluation of prepared URS (for a full list of URS included in the design specifications at the baseline design stage, see **Appendix 8**).

- Punctual (as per agreed schedule) evaluation of completeness and quality of the design specifications submitted to the Customer at the end of a project stage prior to the official submission for approval

- Development / assessment of risk analysis, qualification/validation plans, including project qualification in terms of compliance with EU, FDA, CA, EAU requirements.

- Regular communication with and reporting on the progress and results of works to PQC (Project Quality Coordinator).

III.4. Partial bids or variants will not be accepted.

IV. INQUIRY DELIVERY SITE AND DATE

IV.1. The date of delivery for the contract contemplated hereunder: **from the date when a contract is signed until 15 April 2024,** taking into account an additional period of two weeks for the project qualification (DQ) following formal approval of the design documentation. The qualification process will be considered to have been completed as soon as a report is submitted for approval.

IV.2. The services will be deemed to have been successfully completed when *the design and quality specifications are accepted by the Customer by means of written approval of the documentation, followed by approval of the DQ project qualification report for the Conceptual and Baseline stage*.

IV.3. Place of contract delivery: Starogard Gdański, ul. Pelplińska 19 and online meetings.

V. REQUIREMENTS FOR BIDDERS

Bids submitted by Contractors who demonstrate that they meet the specified requirements will be taken forward to the bid examination and assessment stage. The compliance with the requirements will be assessed based on a 'meet – does not meet' basis. Bidder who fail to meet any of the above requirements will be rejected.

The procedure is open to any Bidders who meet all of the following requirements:

V.1. The contract cannot be awarded to the entities having personal or capital ties to the Customer. Capital or personal ties mean mutual ties between the Customer and the Bidder or persons authorized to contract obligations on behalf of the Customer, or persons performing, on behalf of the Customer, any actions involved in the preparation and performance of the Contractor selection procedure, including in particular:

a) participation in a partnership in the capacity of a partner in a civil-law company or partnership;

b) holding at least 10% of stocks or shares;

c) holding the position of a member of a supervisory or management body, a commercial representative or an attorney;

d) being married to or having lineal consanguinity or direct affinity, collateral consanguinity or affinity to the second degree to, or being adopted by, under the guard or custody of the parties.

In order to fulfil this condition, the Bidder is obliged to send with the bid a signed Declaration on not having personal or capital ties (**Appendix 1** hereto).

V.2. Proof of relevant qualifications

- Experience in similar green-field projects in the pharmaceutical / biotechnological industry or similar high capex (investment) projects;
- English and Polish speaking and writing skills at a communicative level;
- Knowledge of general EU-GMP, FDA, CA, EAU requirements and those relating to Good Manufacturing Practices as specified in the respective Regulation of Minister of Health, knowledge of the qualification and validation procedures as per Annex 11 and Annex 15 of EU-GMP, CFR requirements and the guidelines applicable in the USA, CA, knowledge of other relevant guidelines, i.e. ISPE (PDA or WHO) GAMP, ISO, ASTM.
- Knowledge of the revised Annex 1: Manufacturing of sterile medicinal products will be an advantage;
- Hands-on experience in recording and resolving problems related to designing and qualification of areas, GMP-critical systems (e.g. HVAC, water and clean steam systems, clean gases), computer-based systems and equipment;
- Knowledge in the area of designing areas and preventing cross-contamination as per GMP and EMA's guidelines;
- Knowledge of specific security requirements for facilities and management standards for high-toxic waste, up to and including the rating of OEB5;
- General knowledge of control systems, such as RMS/BMS, PMS, which are used for sterile manufacturing processes;
- General knowledge of computerized systems and data integrity standards;
- Knowledge in the area of microbiology, supervision of manufacturing processes and sterile areas;
- Knowledge of manufacturing issues related to industrial operations involved in the manufacture of sterile products using aseptic processes;
- Knowledge in the field of manufacturing process which is carried out using the RNA technology will be an asset.

A declaration of compliance with the above requirements should be included in the Comments section in Appendix 2 hereto, under your analysis of your compliance with the 'Requirements for Bidders' in section V or as a separate appendix to your response to the Inquiry.

1) The Bidder shall provide, confirmed by relevant entities, positive references in the coordination of a minimum of two analogous "green field" projects of two similar green-field projects (design and release for use of GMP manufacturing areas for parenteral dosage forms, including auxiliary laboratories, i.e. Quality Control Laboratory or Biological Laboratory) during the last 4 years, which were successfully completed (implementation and approval following a GMP inspection)

and

2) The Bidder will provide, confirmed by the relevant entities, positive references for at least 5 validation/qualification projects carried out in aseptic profile factories.

Assessment procedure:

The submitted bids will be evaluated based on:

1. *The bidder's declaration and list of completed services as per Appendix 2 including – dates of completion of services and names of customers.*
2. *CVs of persons who will be involved in the project relating to the required competences specified in section V.2*
3. *An additional declaration provided in the Comments section in Appendix 2 or as a separate appendix containing a declaration describing the bidder's compliance with the requirements of section V.2 (you are welcome to include a summary of specific projects you have carried out, including their brief description, to demonstrate that you do have the required specific experience and knowledge).*

Confirmation of signature of a non-disclosure agreement prerequisite that the technical documentation is made available (Appendices 3 to 8).

Appendix No. 3 - 8 are company secrets and will be released upon signing of the Non-Disclosure Agreement. (**Appendix No. 9)** The bidder should send the completed and signed agreement to the email address barbara.wendolowska@polpharma.com. Upon receipt of a scan of the Non-Disclosure Agreement signed by an authorized person (or persons), in accordance with the representation rules of the respective Bidder, the Procuring Entity will make Exhibits No. 3 - 8 to this Request for Proposal available through digital channels, no later than two business days from the date of receipt of the signed scan of the confidentiality agreement.
The agreement template is attached as an Appendix 9 hereto.

Bids submitted by Contractors who demonstrate that they meet the specified requirements will be taken forward to the bid examination and assessment stage. The compliance with the above requirements will be assessed based on a 'meet – does not meet' basis. Bids submitted by Contractors who fail to meet any of the above requirements will be rejected.

VI. CONTRACT AWARD CRITERIA

VI.1. The following criteria will be used by the Customer for the assessment of bids:
– total net price – 100%

VI.2. The score (P_C) for the Total Net Price will be calculated as follows:

$$P_C = \frac{C_N}{C_B} * 100\ points$$

where:

P_C - score for the Total Net Price

C_N – the lowest net price proposed in the bids which were not rejected

C_B – total net price of the bid being evaluated

Bids with the price given in a currency other than PLN will be converted to PLN at the average exchange rate of the National Bank of Poland as at the final date for the submission of bids.

VI.3. The maximum score that can be awarded to Bidder is 100 points. Calculations will be made to two decimal places.

VII. PLACE AND DEADLINE FOR SUBMISSION OF BIDS

VII.1. The final deadline for submitting bids **is 08 November 2023** by 11:59 p.m.
- bids can be sent in electronic format (as signed electronically or scanned documents by authorised persons) to the following address: barbara.wendolowska@polpharma.com

VII.2. A bid will be considered to have been properly submitted if a complete bid is delivered to the above email address within the time limit stipulated in this section.

VII.3. No bids submitted past the submission deadline will be considered.

VIII. PREPARATION OF QUOTATIONS

VIII.1. Each Bidder should draw up and send only one bid without variances and options using the bid form attached as Appendix 1 hereto.

VIII.2. Each Bidder may be modified or withdrawn prior to the end of the time limit for the submission of bids.

VIII.3. Each Bidder are required to carefully read the information contained in the Inquiry.

VIII.4. The Bidder shall bear the costs of preparation and delivery of the Bid.

VIII.5. For any matters related to this Inquiry, please contact the Customer Barbara Wendołowska, email: barbara.wendolowska@polpharma.com

IX. AMENDMENTS TO THE CONTRACT

IX.1. The Customer reserves the right to make material changes to the provision of the contract, as compared to the bid based on which Contractor was awarded the contract, to the following extent and in the following situations:

IX.1.1. To reflect changes in law that affect the delivery of the services covered by the Contract (in particular changes in VAT rates);

IX.1.2. To improve technical parameters of the Contract in line with new solutions brought about by technological advancements, without any effects on the gross flat rate;

IX.1.3. To extend the deadline for the delivery of the services covered by the Contract due to additional works which need to be carried out to ensure proper delivery of the services covered by the Contract and which the Customer, while exercising due diligence, could not have foreseen beforehand, subject to section IX.1.6 below;

IX.1.4. To extend the deadline for the delivery of the services covered by the Contract due to force majeure event(s), with any consequences of such an extension;

IX.1.5. To change the parameters of the services covered by the Contract without altering the nature of the Contract – technology-related changes, in particular: the need to deliver the services covered by the Contract using other solutions – in terms of technology or materials – than those specified in the Request for Quotation in the event that the use of the original solutions could lead to non-delivery or improper delivery of the services covered by the Contract, subject to section IX.1.7. below;

IX.1.6. To make changes with respect to additional deliveries or services to be provided by Contractor, which are not covered by the Contract, as long as they are necessary and when all of the following requirements are met:

– Contractor cannot be replaced due to economic or technical reasons, in particular relating to the interchangeability or interoperability of equipment, services or systems contracted under the original Contract,
– Contractor replacement could cause significant inconvenience or a material increase in costs for the Customer,
– each subsequent change does not exceed 50% net of the original Contract net amount;

IX.1.7. To make changes without altering the nature of the Contract, when all of the following requirements are met:
– the Contract needs to be changed due to circumstances which could not have been foreseen by the Customer while exercising due diligence,
– the change does not exceed 50% of the original Contract net amount;

IX.1.8. To replace the Contractor with a new contractor:

– as a result of merger, division, transformation, bankruptcy, restructuring or purchase of Contractor or its enterprise as long as the new contractor meets the conditions for participation in the procedure, there are no grounds for its exclusion and the change does not result in other material amendments to the Contract,
– as a result of the Customer taking over Contractor's obligations towards its subcontractors;

IX.1.9. To amend the Contract without altering the nature of the Contract, when the total value of the amendments is less than EUR 215,000 and at the same time it is less than 10% of the original Contract net amount.

IX.2. The Customer can also make non-material amendments to the Contract as compared to the bid based on which Contractor was awarded the Contract.

IX.3. Any amendments to the Contract will be made in the form of an annex signed by both parties and will require approval from the Customer.

X. ADDITIONAL INFORMATION

X.1. Until the end of the time limit for the submission of bids, the Customer reserves the right to amend or add new information to this Inquiry Inquiry.

X.2. The submitted bids will remain valid and binding for 90 days from the end date of the time limit for the submission of bids, referred to in Section VII. 1

X.3. The provision of the contract draft version to be used in the negotiations will be at the sole discretion of the Customer. The draft version will be presented after the Contractor has been selected.

X.4. The Supplier shall pay contractual penalties to the Customer:

a) for any delay in delivery of the subject of the contract for each commenced day of such delay unless the delay has been caused by the Customer;

b) for incorrect delivery of the contract;

c) for incomplete delivery of the contract.

X.5. The Supplier consents to the deduction of the contractual penalties directly at the time of settlement of the VAT invoice for the completed delivery.

XI. LIST OF APPENDICES

The following appendices are attached to this Inquiry:

Appendix number	Appendix title
Appendix 1	Bid Form
Appendix 2	Declaration of compliance with the eligibility criteria for the participation in the procedure
Appendix 3	Summary of reference product characteristics
Appendix 4	Description of the production area/process
Appendix 5	Floor plan of the site divided into individual areas and information on their surface area
Appendix 6	List of qualification/validation and quality documentation included in the scope of the baseline design
Appendix 7	List of documents included in the design specifications
Appendix 8	list of URS included in the quality/qualification documentation.
Appendix 9	Non-disclosure agreement.

BID FORM

Bidder:

Full name (business name) or name and surname	
Registered office/place of residence/address of the principal place of business	
Email address for the Customer to send correspondence related to the Inquiry	
NIP [Taxpayer ID Number]	
REGON [Statistical ID Number]	
Phone number	
Contact person for the Customer	

We offer to perform the subject of the request for proposal in terms of providing services for the development, evaluation of the design documentation of the newly designed manufacturing area for investigational medicinal products and small commercial batches, in accordance with the requirements of the Request for Quotation, for a total price:

net amount: PLN/EUR/USD* …… *(select the relevant currency)

applicable VAT (if applicable): ……% …… PLN/EUR/USD*

gross amount: PLN/EUR/USD* ……

(say: ……...……..)

We also declare that:

a. We have read the Inquiry and appendices thereto, we raise no objections and we have obtained the information necessary to prepare our bid;

b. Our bid price includes a lump sum remuneration that covers all the obligations of the future Contractor as necessary to deliver the contract referred to hereunder;

c. Our bid will remain valid and binding for 90 days from the end date of the time limit for the submission of bids;

d. We are/We are not a related party within the meaning of Commission Regulation (EC) No. 1126/2008;

e. We represent that the following circumstances do not apply to us:

- as described in Article 7(1) of the Act of 13 April 2022 on Special Measures to Counteract Support for the Aggression against Ukraine and to Protect National Security;
- as described in Article 5k of the Council Regulation (EU) No 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine.

……	……
(place and date)	(signature(s) of person(s) authorized to submit statements of will on behalf of the Bidder)

Customer:
Warszawskie Zakłady Farmaceutyczne
Polfa S.A.

ul. Karolkowa 22/24

01-207 Warszawa

Bidder Declaration

OF COMPLIANCE WITH THE ELIGIBILITY CRITERIA FOR THE PARTICIPATION IN THE PROCEDURE

By submitting a bid for **the provision** of services for the development, evaluation and implementation of an integrated Quality system in the newly established manufacturing area of investigational medicinal products medicinal products, we declare as follows:

I declare as follows:

INFORMATION ON THE BIDDER:

I declare that we meet the conditions for participation in the procedure as specified by the Customer in section V of this Inquiry:

- participation in the coordination of two similar green-field projects during the last 4 years, which were successfully completed (implementation and approval following a GMP inspection);
- participation in at least 5 validation/qualification projects done in aseptic factories

SUMMARY OF COMPLETED PROJECTS

No.	**Scope of green-field project**	**Implementation period** **(from – to)** (day – month – year)	**Customer** (name, address)	**GMP inspection result**
1.				
2.				
3.				
4.				

No.	**Subject and scope of the validation / qualification project carried out in factories with aseptic profile**	**Implementation period (from – to)** (day – month – year)	**Customer** (name, address)
1.			
2.			
3.			
4.			
5.			

COMMENTS

…….....…..…….., date: ….....…..…..……

.....

(signature of the representative

of Bidder/ Bidder's Representative)

REFERENCE PRODUCT:	**1) Spinraza 12 mg solution for injection**	**2) Leqvio 284 mg solution for injection**	**3) Ozempic (semaglutide) solution for injection in pre-filled pen** **4) WEGOVY (semaglutide) injection, for subcutaneous use – single dose injector**
PACKAGING	**Glass vial**	**Pre-filled syringe**	**Cartridge / Pre-filled syringe**
DETAILED DESCRIPTION OF THE PACKAGING	5 ml in a Type I glass vial with bromobutyl rubber stopper and an aluminium over-seal and plastic cap	1,5 ml solution in PF (glass type I) **(1)** equipped with a plunger (made of fluoretec coated bromobutyl rubber), needle and rigid needle shield **(1)**	1.5 ml or 3 ml glass cartridge (type I glass) closed at the one end with a rubber plunger (chlorobutyl) and at the other end with an aluminium cap with a laminated rubber sheet (bromobutyl/polyisoprene) inserted. The cartridge is assembled into a disposable pre-filled pen made of polypropylene, polyoxymethylene, polycarbonate and acrylonitrile butadiene styrene.
STORAGE CONDITIONS (FINISH PRODUCT)	Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light	This medicinal product does not require any special storage condition. Do not freeze	36 months when stored in a refrigerator (2°C to 8°C) and kept away from the cooling element, protected from light
STORAGE CONDITIONS (API)	24 months under long term conditions at **-20 ± 5°C** and for up to 6 months under accelerated conditions at 5 ± 3°C	36 months at **-20 ± 5°C**	60 months under long term conditions **at -20 ± 5°C.** Under accelerated conditions at 5 ± 3°C no change over 6 m time was seen
PURPOSE	Used in treatment of spinal muscular atrophy (SMA) – a rare neuromuscular disorder. The recommended dosage is 12 mg (5 ml) per administration. Spinraza treatment should be initiated as early as possible after diagnosis with 4 loading doses on Days 0, 14, 28 and 63. A maintenance dose should be administered once every 4 months thereafter. **(3)**	Is indicated in treatment of adult patient with primary hypercholesterolaemia. The recommended dose is 284 mg inclisiran administered as a single subcutaneous injection: initially, again at 3 months, followed by every 6 months.	Ozempic is indicated for the treatment of adults patient with inadequately controlled diabetes type 2. One injection per week. WEGOVY is indicated for the treatment of adults patient with obesity as an adjunct to low-calorie diet and increased physical activity. One injection per week as long as the treatment last.
DESCRIPTION OF MEDICINAL PRODUCT	1) Nusinersen is **an antisense oligonucleotide (ASO**) which increases the proportion of exon 7 inclusion in survival motor neuron 2 (SMN2) messenger ribonucleic acid (mRNA) transcripts by binding to an intronic splice silencing site (ISS-N1) found in intron 7 of the SMN2 pre-messenger ribonucleic acid (pre-mRNA). 2) By binding, the ASO displaces splicing factors, which normally suppress splicing. 3) Displacement of these factors leads to retention of exon 7 in the SMN2 mRNA and hence when SMN2 mRNA is produced, it can be translated into the functional full length SMN protein. **(5)**	1) Inclisiran is a cholesterol-lowering, **double-stranded, small interfering ribonucleic acid (siRNA),** conjugated on the sense strand with triantennary N-acetylgalactosamine (GalNAc) to facilitate uptake by hepatocytes. 2) In hepatocytes, inclisiran utilises the RNA interference mechanism and directs catalytic breakdown of mRNA for proprotein convertase subtilisin kexin type 9. This increases LDL-C receptor recycling and expression on the hepatocyte cell surface, which increases LDL-C uptake and lowers LDL-C levels in the circulation. **(6)**	Semaglutide is a long acting analogue of human glucagon like-1 peptide i.e. an Aib8, Arg34-GLP-1(7-37) analogue substituted on the ε-amino group of the lysine residue in position 26 with an (S)-22,40-dicarboxy-10,19,24-trioxo-3,6,12,15-tetraoxa-9,18,23-triazatetracontan-1-oyl side chain. The side chain consists of two 8-amino-3,6-dioxaoctanoic acid (ADO) spacers, one γ-glutamic acid (Glu) spacer, and a fatty diacid (1,18-octadecanedioic acid). **(7)**
DRUG FORM	Solution for injection	Solution for injection	Solution for injection

REFERENCE PRODUCT:	**1) Spinraza 12 mg solution for injection**	**2) Leqvio 284 mg solution for injection**	**3) Ozempic (semaglutide) solution for injection in pre-filled pen** **4) WEGOVY (semaglutide) injection, for subcutaneous use – single dose injector**
MANUFACTURING PROCES DESCRIPTION	1. Receipt and storage of the drug substance at manufacturing site, temperature equilibration of the drug substance 2. Excipient dispensing and WFI water for artificial cerebrospinal fluid preparation 3. Artificial cerebrospinal fluid preparation 4. Active substance concentrate preparation in aCSF in a container, 5. Compounding and mixing to ensure homogeneity 6. Filters are flushed with waters and than with bulk product to reduce bioburden, get rid of leachables 7. Sterilizing filtration, 8. Aseptic vial filling, stoppering and crimping and 9. 100% visual inspection of filled vials	1. Receipt and storage of the drug substance at manufacturing site, temperature equilibration of the drug substance 2. Dissolution of the active substance in WFI 3. pH adjustment with phosphoric acid or sodium hydroxide, 4. Sterilizing filtration, 5. Aseptic pfs filling, 6. Stoppering	1. Dissolution of all excipients and diluted with WFI to obtain the desired weight. 2. Addition of API to the solution 3. pH adjustment by diluted HCl or NaOH 4. Sterile filtration **to stainless steel filling tank** 5. Aseptic filling into sterilized and depyrogenated 1.5 mL cartridge 6. Inspection of cartridges and assemble in the PDS290 pen injector 7. Labelling and packing in cartons
ASEPTIC PROCESS VS TERMINAL STERILIZATION	Sterilizing filtration (Aseptic proces)	Sterilizing filtration (Aseptic proces)	Sterilizing filtration (Aseptic proces)
COMMON CRITICAL ELEMENTS IN THE PROCESS	N/A (Disposable sets dedicated to the product)	N/A (Disposable sets dedicated to the product)	N/A (Disposable sets dedicated to the product)
SINGIEL USED ITEMS	YES	YES	NO (tbd)

General description of the production area/process

1. General description

The manufacturing program for the new area will include the manufacture of sterile dosage forms such as solutions. Once manufactured, the dosage forms will be dispensed into the following types of containers:

- glass vials,
- prefilled syringes,
- cartridges.

Products characteristics:

- Pharmaceutical form of the product: solutions, emulsions, lyophilisates (in the future)
- pH 2-12
- Density: max. 1.2 g/cm^3.
- Viscosity: max. 100 cP.
- The product may be photosensitive,
- Water-based product for WFI injections
- Batch size: min. 1l - max. 50l
- Product temperature 5°C to 30°C

Work plan:

It is assumed that the work plan will be as follows:

- 1 shift/day,
- 5 working days/week,
- 45 working weeks/year.

2. Warehousing and sample collection area

The process of controlling the starting materials will be carried out in the existing storage area. In the course of the project, the storage area and the planned process will have to be analyzed and the necessary procedures as well as the required additional technical measures, if necessary, will have to be defined.

3. Pilot-scale manufacturing area

The Pilot Plant features space for the installation of the following main processing equipment:

Processing and auxiliary equipment included in the project:
- insulator for weighing
- UDAF – weighing room
- solution preparation system – (SUS)
- filtration unit
- autoclave
- VHP chamber
- automatic parts washer
- filling line (vials/PFS/cartridges)
- balances;
- isolated transport system
- decontamination shower (MS)
- mobile UDAF
- serialization module (optional)

4. Weighing area

The weighing of excipients and non-critical APIs as well as high-toxic >OEB3 APIs will take place in an isolator installed in the solution preparation room. The isolator will be provided with the following balances:

- laboratory balance with a weighing range of up to 100 g,
- tabletop balance with a weighing range of up to 3 kg

Starting materials will be delivered from the warehouse through pass boxes, using appropriate outer packaging cleaning procedures. All materials (products/raw materials) intended for use in a GMP area will be transported in a secure and controlled manner, in accordance with the procedures. Given the quantity of materials to be weighed, weighing operations will be carried out manually.

Given the need to weigh out small quantities of active materials, weighing operation in an isolator will be carried out manually. The materials weighed out into containers provided with a divided valve will be transferred for further processing. Any remaining unused materials will be secured in the isolator with additional

packaging, removed from the isolator, labelled in accordance with the procedures and transported back to the warehouse. Once the weighing process is completed, the isolator will be washed using a WIP system.

5. **Preparation of the solution**

In the solution preparation room, there is a disposable (single-use) solution preparation system including holders and stirrer drives.

Given the specific nature of work in such areas, the solution preparation system will make it possible to use any configuration of connections between tanks. Solutions will be prepared under laminar air flow (LAP) conditions. Depending on the configuration required due to the technology, tanks will be connected using flexible connections. Once pre-filled with water for injections, the solution preparation tank will be manually loaded through a hatch, funnel with substances classified as OEB<3 materials. It is expected that ethanol, acetic acid (product component) will be used on the line. During the preparation of a solution, alcohol will be added manually to the tank and it may constitute no more than 10% of the total volume of the product. Dosing operations will be carried out through a hatch. Only after low-toxicity substances are loaded, highly toxic APIs will be added using a system for isolated transport.

Toxic substances (OEB≥3) will be loaded using a container provided with the passive side of a divided valve connected to a stub pipe of the solution preparation tank provided with the active side of the valve. During control operations critical processing parameters will be recorded automatically or semi-automatically (i.e. solution temperature in the tank, pressure in the tank, transfer pressure, stirring speed, readings of sensors installed on the tanks). Once prepared, the solution will be pumped using compressed gas (nitrogen, compressed air) or a peristaltic pump towards the filling line which will be located in a class B room. The filtration set-up will consist of:

- pre-filter, 0.45 μm
- sterilizing filter, 0.2 μm

All materials will be transferred into Filling Rooms using two methods:

- VHP chamber
  - equipment not in direct contact with the product
  - filters, flexible connections, SUS equipment

- pass-through autoclave – materials secured with double paper sleeves:
  - stoppers and caps;
  - removable components of filling machines - autoclaves

Materials will be removed outside through:

- finished product through MH (Mouse Hol and conveyor belt system).
- other materials through a pass box

Packaging materials/machine components will be transported within the area on a UDAF-equipped drive-through trolley using a multi-bag solution for protection during transport, where applicable. Materials will be unloaded from the autoclave or VHP chamber under UDAF conditions.

6. **Filling**

Products will be filled into the following immediate packages:

- vials,
- prefilled syringes,
- cartridges.

Finished solution will be transported into the filling room directly to the filling line equipped with a filtration set-up. It should be possible to carry out filling and closing operations in a protective nitrogen atmosphere. All operations involving an open product, such as filling, stoppering will be carried out under UDAF conditions – class A. Products filled in pre-filled syringes will be collected from the filling machine directly in the filling room.

7. **IPC**

The following parameters will be tested at the IPC laboratory:

- pH
- viscosity
- osmolality
- packaging weight
- packaging integrity.

8. **Equipment washing operations**

Dirty accessories to be washed will be transported to the dirty equipment warehouse. Next, the accessories will be transferred to the washing room and clean equipment warehouse, where small accessories will be washed in a pass-through washer and large accessories – in a large capacity washing station. Clean

accessories will be transferred (large accessories will be transported on trolleys) and stored in the clean equipment warehouse room. Once washed and dried, the accessories that need to be sterilized will be packed into double paper sleeves, where applicable. Non-SUS line components will be washed in the washing room and sterilized in an autoclave or decontaminated in VHP chamber.

9. Final packing operations

Packing operations in the Pilot Plant will be carried out manually, divided into the following stages:

- inspection (visual inspection),
- labelling,
- packing into individual cardboard boxes, together with a leaflet,
- serialization,
- packing into bulk boxes.

Packaging will take place in a functioning area. In the course of the project, the packing area and the planned process will have to be analyzed and the necessary procedures, as well as the required additional technical measures, if necessary, defined.

100% vials found to have the following defects should be rejected:

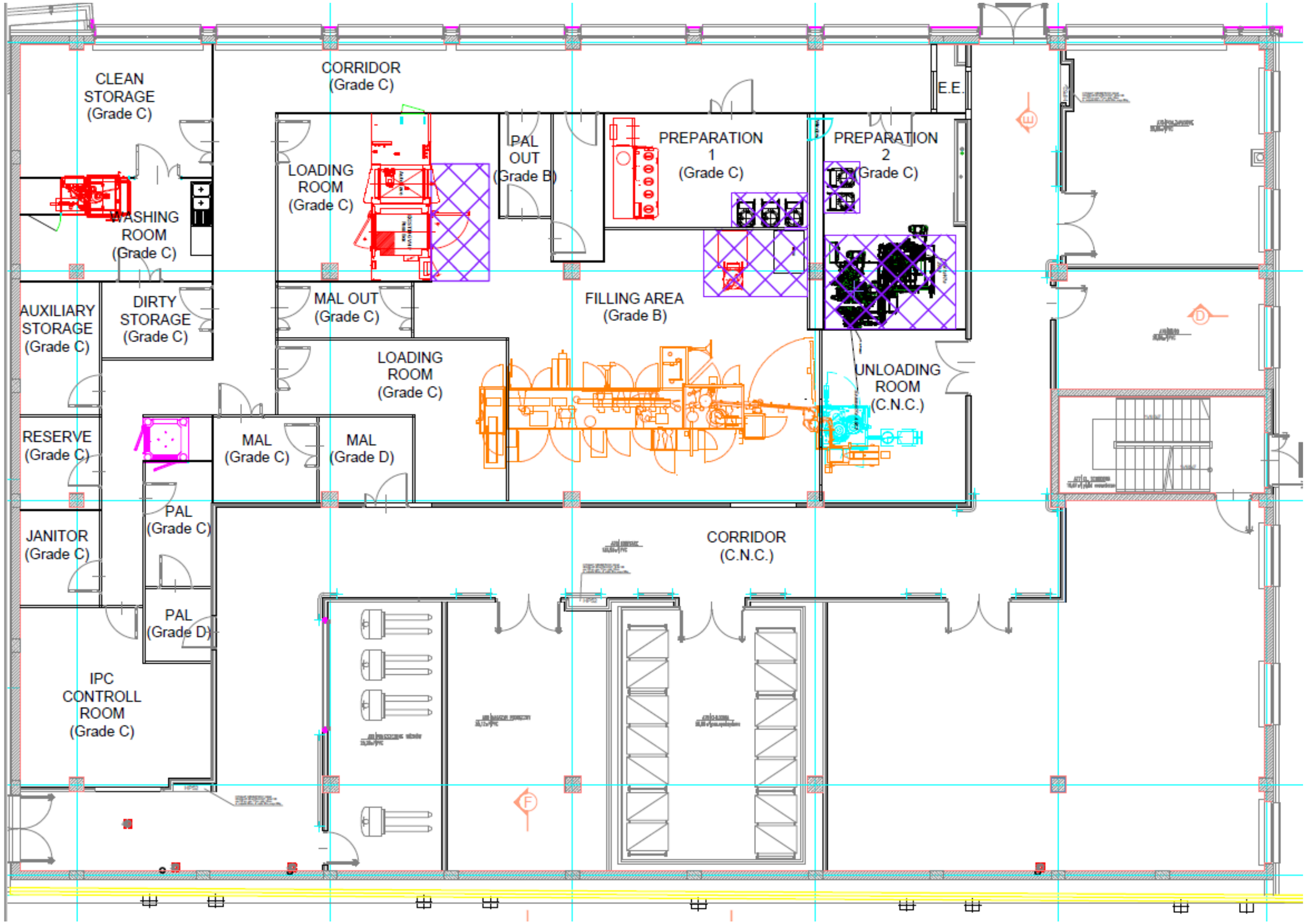
1) Caps/stoppers for closing vials (packaging):

- position and color of a flip-off cap,
- color of a cap,
- missing stopper,
- dented or scratched cap,
- defective cap sealing,
- scratches, cracks, dirt on walls and the bottom.

2) Solutions (product):

- moving particles (glass, metal, fibers),
- floating particles,
- heavy particles at the bottom of a vial,
- liquid level.

Packing operations for products that require dedicated packaging and cannot be packed manually will be outsourced to outside providers. A serialization module will be used for the serialization process. To minimize the risk of confusion between batches/products, packaging operations will be carried out only for one batch at a time, in conformity with Polpharma Group’s internal procedures. Materials required for packaging operations – labels, cardboard boxes, leaflets, bulk boxes will be delivered from the Warehouse directly to the secondary packaging operations rooms, where they will be placed on appropriate devices or moved onto buffer surfaces provided in these rooms. Bulk boxed containing finished products will be stacked onto pallets. Pallets will be transported via pass box to the warehouse.


CLEAN STORAGE (Grade C)
CORRIDOR (Grade C)
E.E.
WASHING ROOM (Grade C)
LOADING ROOM (Grade C)
PAL OUT (Grade B)
PREPARATION 1 (Grade C)
PREPARATION 2 (Grade C)
AUXILIARY STORAGE (Grade C)
DIRTY STORAGE (Grade C)
MAL OUT (Grade C)
FILLING AREA (Grade B)
LOADING ROOM (Grade C)
UNLOADING ROOM (C.N.C.)
RESERVE (Grade C)
MAL (Grade C)
MAL (Grade D)
PAL (Grade C)
JANITOR (Grade C)
PAL (Grade D)
CORRIDOR (C.N.C.)
IPC CONTROLL ROOM (Grade C)

		VALIDATION	
No.	**AREA/DRAWING TITLE**	**CONCEPTUAL DESIGN**	**BASELINE DESIGN**
		YES/NO	**YES/NO**
1	Review/Update of the Master Validation Plan – single assessment/correction of the document at a given stage.	YES	YES
2	Review/Update of the System Impact Assessment (SIA) – single assessment/correction of the document at a given stage.	YES	YES
3	Review/Update of the Risk Analysis – double assessment/correction of the document at a given stage.	YES	YES
4	Review/Update of the DQ Plan – single assessment/correction of the document at a given stage.	YES	YES
5	Review/Update of the DQ Plan – GMP Review single assessment/correction of the document at a given stage.	YES	YES
6	Review/Update of appendices to the DQ Plan – GMP Review - double assessment/correction of the document at a given stage.	YES	YES
7	Review/Update of the DQ Plan – URS Review - single assessment/correction of the document at a given stage.	YES	YES
8	Review/Update of appendices to the DQ Plan – URS Review - double assessment/correction of the document at a given stage.	YES	YES
9	Review/Update of the DQ Plan – Eurasia GMP Review - single assessment/correction of the document at a given stage.	YES	YES
10	Review/Update of appendices to the DQ Plan – Eurasia GMP Review - single assessment/correction of the document at a given stage.	YES	YES
11	Review/Update of the DQ Plan – FDA GMP Review - single assessment/correction of the document at a given stage.	YES	YES
12	Review/Update of appendices to the DQ Plan – FDA GMP Review - single assessment/correction of the document at a given stage.	YES	YES
13	Review/Update of the DQ Plan – CA GMP Review - single assessment/correction of the document at a given stage.	YES	YES
14	Review/Update of appendices to the DQ Plan – CA GMP Review - single assessment/correction of the document at a given stage.	YES	YES
15	Development of the final DQ report.	YES	YES
16	Containment Strategy	YES	YES

List of project Deliverables – Concept design

Type	Description	Type of document	Support file	Concept Design	Language
General	Conceptual design including all necessary disciplines narratives	Concept report Narrative + original revised deliverables	Word + others	Y	E/P
General	Project Execution Plan and Coordination Procedure	Document	Word	Y	E
General	Cost Estimate +/- 20% with narrative and assumptions (at the end of Conceptual Consolidation)	Narrative and tables	Word + Excel	Y	E/P
General	Interactive Planning Session to develop project schedule	Meeting Report with attachment and pictures	Word	Y	E/P
General	Time Schedule) in MS Project	Bar Chart	MS Project	Y	E/P
General	Vendors list	Matrix	Excel	Y	E/P
General	URS for the facility	Narrative	Word + attachments	Y	E/P
General	GMP review	Procedure Template	Word + attachments	Y	E/P
General	HAZOP and Safety design reviews	Procedure Template	Word + attachments	Y	E/P
General	Facility containment philosophy/strategy	Conceptual Narrative	Word + attachments	Y	E/P
General	Design qualification (DQ) / Protocol and execution report	Procedure Template	Word + attachments	Y	E/P
General	SIA - System Impact Assessment	Procedure Template	Word + attachments	Y	E/P
General	Validation Master Plan	Template	Word + attachments	Y	E/P
General	Document List	Table	Excel	Y	E/P
General	Weekly and Monthly reporting	Narrative	Word + attachments	Y	E/P
Civil	General Lay-Out (Site Plot Plan, each level) - 1st issue for conceptual	Table	Excel	Y	E/P
Civil	General Lay-Out (Site Plot Plan, each level) - 1st issue for conceptual	Drawing	DWG	Y	E/P
Civil	Temporary facilities and construction site layout / arrangement	Drawing	DWG	Y	E/P
Civil	General Layout (Building and for each level)	Drawing	DWG	Y	E/P
Civil	Plant 3D / General rendering	3D vision	Autocad or similar	Y	E/P
Civil	Civil Lay-Outs - dimensioned (for each level)	Drawing	DWG	Y	E/P
Civil	Finishing Abacus for internal and external works - (1st issue for conceptual)	Specification	Word+Excel	Y	E/P
Civil	External Areas Lay-out (roads, parking, green area, fence, etc) - (1st issue for conceptual)	Revision of L&P documents		Y	E/P
Civil	Sewer and drainage system Lay-Out (including water treatment/collection drawings)	Drawing	DWG	Y	E/P
Civil	Metallic structures One line drawing	Drawing	DWG	Y	E/P
Process	Process Description (PFD attacched) - 1st issue for conceptual	Conceptual and Detailed Narrative	Word	Y	E/P
Process	Capacity Planning with definition of all process conditions to determine batch size, number of batches, operating modes, buffer storages areas, etc among other process conditions - 1st issue for conceptual	Narrative and tables	Word+Excel	Y	E/P
Process	Equipment Lay-Out - 1st issue for conceptual	Drawing	DWG	Rev	E/P
Process	Process and Utillities Equipment List - 1st issue for conceptual	Table	Excel	Y	E/P
Process	Equipment List	Table	Excel	Y	E/P
Process	Material Flow Lay-Out - 1st issue for conceptual	Drawing	DWG	Y	E/P
Process	Personnel flow Lay-Out - 1st issue for conceptual	Drawing	DWG	Y	E/P
Process	Cleannes layouts - 1st issue for conceptual	Drawing	DWG	Y	E/P
Process	Process flowsheets (for all process lines) with material balances - 1st issue for conceptual	Drawing	DWG	Y	E/P
Process	User point Lay-Out (for each level and all services) - 1st issue for conceptual	Drawing	DWG	Y	E/P
Process	Pure fluids PFDs and technical utilties PFDs - 1st issue for conceptual	Drawing	DWG	Y	E/P
Process	Fluid Consumption List (summary and detailed user by user) with definition of assumptions - 1st issue for conceptual	Table	Excel	Y	E/P
Process	Fluid List - 1st issue for conceptual	Table	Excel	Y	E/P

Process	Process Equipment Specification (only for lon lead items in the concept phase)	Specification	Word	Y	E/P
Mechanical	Technical Utilities Systems Description - 1st issue for conceptual	Narrative	Word + attachments	Y	E/P
Mechanical	Technical utilities PFD (fluid dedicated) - 1st issue for conceptual	Drawing	DWG	Y	E/P
HVAC	HVAC systems Description - 1st issue for conceptual	Narrative	Word + attachments	Y	E/P
HVAC	Detailed design criteria room by room (to be included in the conceptual for rev. 0)	Narrative and tables	Word + Excel	Y	E/P
HVAC	Pressure Lay-Outs - 1st issue for conceptual	Drawing	DWG	Y	E/P
HVAC	Area Classification Lay-Out - 1st issue for conceptual	Drawing	DWG	Y	E/P
HVAC	HVAC flow diagram - 1st issue for conceptual	Drawing	DWG	Y	E/P
HVAC	P&ID HVAC	Drawing	DWG		E/P
HVAC	HVAC systems zoning - 1st issue for conceptual	Drawing	DWG	Y	E/P
HVAC	Duct Oneline Lay-Out (for each level, planimetric distribution)	Drawing	DWG	Y	E/P
Electrical	Electrical systems description - 1st issue for conceptual	Narrative and attachments	Word	Y	E/P
Electrical	Electrical Load List (by user and summary) - 1st issue for conceptual	Table	Excel	Y	E/P
Electrical	Electrical plant Architecture / One line diagramme - 1st issue for conceptual	Drawing	DWG	Y	E/P
Electrical	Elettrical Classification (ATEX) Technical Report	Specification	Word	Y	E/P
Electrical	Electrical user points layouts - 1st issue for conceptual	Drawing	DWG	Y	E/P
Automation	I&C and Automation systems description - 1st issue for conceptual	Narrative + attachments	Word + attachments	Y	E/P
Automation	Control and monitoring System Architecture (diagram and description) - 1st issue for conceptual	Narrative	Word	Y	E/P

List of project Deliverables – Basic design

Type	Description	Type of document	Support file	Basic Design	Language
General	Basic desing final report (book)	Report Narrative+attachments	Word + others	Y	E/P
General	Building permit design documentation organizing all necessary deliverables in sections as per local regulations	Report Narrative+attachments	Word + others	Y	E/P
General	Authorities permitting chart (describing steps, milestones and duration along the project)	Flow Chart	Visio	Y	E/P
General	Project Execution Plan and Coordination Procedure	Document	Word	Rev	E
General	Cost Estimate +/- 10% with narrative and assumptions (with risk analysis)	Narrative and tables	Word + Excel	Y	E/P
General	Interactive Planning Session to develop project schedule	Meeting Report with attachment and pictures	Word	Rev	E/P
General	Time Schedule) in MS Project	Bar Chart	MS Project	Y	E/P
General	Vendors list	Matrix	Excel	Rev	E
General	Procurement Plan	Matrix	Excel	Y	E/P
General	URS for the facility	Narrative	Word + attachments	Y	E/P
General	GMP review	Procedure Template	Word + attachments	Y	E/P
General	HAZOP and Safety design reviews	Procedure Template	Word + attachments	Y	E/P
General	Facility containment philosophy/strategy	Conceptual Narrative	Word + attachments	Rev	E/P
General	Design qualification (DQ) / Protocol and execution report	Procedure Template	Word + attachments	Y	E/P
General	SIA - System Impact Assessment	Procedure Template	Word + attachments	Rev	E/P
General	Validation Master Plan	Template	Word + attachments	Rev	E/P
General	Facility Commissioning Plan	Schedule Narrative	Word + attachments	Y	E/P
General	Plant / space study coordination sections	Drawing	DWG	Y	E/P
General	Document List	Table	Excel	Rev	E/P
General	General Specification for Vendors Documentation (to be customized to each tender package and for each requisition)	Specification	Word	Y	E/P
General	Weekly and Monthly reporting	Narrative	Word + attachments	Y	E/P
Civil	Civil works narrative for Building Permit	Report Narrative	Word	Y	E/P
Civil	General Lay-Out (Site Plot Plan, each level) - 1st issue for conceptual	Table	Excel	Rev	E/P
Civil	General Lay-Out (Site Plot Plan, each level) - 1st issue for conceptual	Drawing	DWG	Rev	E/P
Civil	Temporary facilities and construction site layout / arrangement	Drawing	DWG	Rev	E/P
Civil	General Layout (Building and for each level)	Drawing	DWG	Rev	E/P
Civil	Plant 3D / General rendering	3D vision	Autocad or similar	Rev	E/P
Civil	Civil Lay-Outs - dimensioned (for each level)	Drawing	DWG	Rev	E/P
Civil	Pharma - finishing Lay-outs (for each level)	Drawing	DWG	Y	E/P
Civil	False ceiling Lay-outs (for each level)	Drawing	DWG	Y	E/P
Civil	Structural Lay-Outs (for each level) and sections	Drawing	DWG	Y	E/P
Civil	Civil works Sections (as requested by authority and scope of work)	Drawing	DWG	Y	E/P
Civil	Civil Views (as requested by authority)	Drawing	DWG	Y	E/P
Civil	Live Load distribution Lay-outs	Drawing	DWG	Y	E/P
Civil	Foundations Lay-out with all necessary details	Drawing	DWG	Y	E/P
Civil	Piling Lay-outs (if necessary)	Drawing	DWG	Y	E/P
Civil	Structure sizing/sizing criteria	Report narrative	Word	Y	E/P
Civil	Structural Calculation with reference drawings/	Report narrative	Word	Y	E/P
Civil	Finishing Abacus for internal and external works - (1st issue for conceptual)	Specification	Word+Excel	Rev	E/P
Civil	External Areas Lay-out (roads, parking, green area, fence, etc) - (1st issue for conceptual)	Revision of L&P documents		Rev	E/P
Civil	Sewer and drainage system Lay-Out (including water treatment/collection drawings)	Drawing	DWG	Rev	E/P
Civil	Metallic structures One line drawing	Drawing	DWG	Rev	E/P

Civil	Civil works material requisition - MTO included	Specification	Word	Y	E/P
Civil	Clean rooms Finishing Job description - MTO included	Specification	Word + Excel	Y	E/P
Civil	Doors and modular partition for pharma rooms Specification (furniture and integrated pass-box)	Specification	Word	Y	E/P
Civil	Doors, walls, floors lining and ceilings Specification for offices, laboratories, technical and production areas	Specification	Word	Y	E/P
Civil	Floors / slabs specifications	Specification	Word	Y	E/P
Civil	External building walls, windows, gates, fixtures materials specifications	Specification	Word	Y	E/P
Civil	Metallic structures Specification / assumed as reference L&P documents	Specification	Word	Y	E/P
Civil	Paintings Specification	Specification	Word	Y	E/P
Civil	Inox furniture specification (pharma related, non pharma related)	Specification	Word	Y	E/P
Civil	Furniture specification and material requisition(with rendering drawings and MTOs)	Specification	Word	Y	E/P
Civil	Offices furniture specification and material requisition(with rendering drawings and MTOs)	Specification	Word	Y	E/P
Process	Process Description (PFD attacched) - 1st issue for conceptual	Conceptual and Detailed Narrative	Word	Rev	E/P
Process	Capacity Planning with definition of all process conditions to determine batch size, number of batches, operating modes, buffer storages areas, etc among other process conditions - 1st issue for conceptual	Narrative and tables	Word+Excel	Rev	E/P
Process	Equipment Lay-Out - 1st issue for conceptual	Drawing	DWG	Rev	E/P
Process	Process and Utillities Equipment List - 1st issue for conceptual	Table	Excel	Rev	E/P
Process	Equipment List	Table	Excel	Rev	E/P
Process	Material Flow Lay-Out - 1st issue for conceptual	Drawing	DWG	Rev	E/P
Process	Personnel flow Lay-Out - 1st issue for conceptual	Drawing	DWG	Rev	E/P
Process	Cleannes layouts - 1st issue for conceptual	Drawing	DWG	Rev	E/P
Process	Process flowsheets (for all process lines) with material balances - 1st issue for conceptual	Drawing	DWG	Rev	E/P
Process	User point Lay-Out (for each level and all services) - 1st issue for conceptual	Drawing	DWG	Rev	E/P
Process	Pure fluids PFDs and technical utilties PFDs - 1st issue for conceptual	Drawing	DWG	Rev	E/P
Process	Pure fluids P&ID (dedicated CS, WFI e PW)	Drawing	DWG	Y	E/P
Process	Process unit P&ID (each)	Drawing	DWG	Y	E/P
Process	Line List for all fluids (process, process utilities and technical utilities)	Table	Excel	Y	E/P
Process	Fluid Consumption List (summary and detailed user by user) with definition of assumptions - 1st issue for conceptual	Table	Excel	Y	E/P
Process	Fluid List - 1st issue for conceptual	Table	Excel	Rev	E/P
Process	Pure fluids generation systems Specification	Specification	Word	Y	E/P
Process	Pure fluids storage and distribution systems Specification	Specification	Word	Y	E/P
Process	Pure fluids equipment for storage and distribution Datasheet	Specification	Excel	Y	E/P
Process	Pure fluids functional Specification	Specification	Word	Y	E/P
Process	Process Equipment Data Sheet	Specification	Excel	Y	E/P
Process	Process Equipment Specification (only for lon lead items in the concept phase)	Specification	Word	Rev	E/P
Process	Pharma Process Equipment Data Sheet	Specification	Excel	Y	E/P
Process	Pharma Process Equipment Material Requisitions (for all new equipment)	Specification	Word	Y	E/P
Process	Solution Preparations systems Material requisition - MTO included (the MR will include the relevant portion of I&C design - see automation section)	Specification	Word + Excel	Y	E/P
Process	Pure Fluids Material requisition - MTO included (the MR will include the relevant portion of I&C design - see automation section)	Specification	Word + Excel	Y	E/P
Process	Process Utilities and Solutions preparation systems 3D models	Specification	Word + Excel	Y	E/P
Process	Piping Lay-Out for process utilities- (for each level)	Drawing	DWG	Y	E/P
Process	Piping Lay-Out for process - (for each suite)	Drawing	DWG	Y	E/P
Process	Sanitary Piping / Process piping components specification(s) and typcals/details	Specification	Word + Excel	Y	E/P
Mechanical	Technical Utilities Systems Description - 1st issue for conceptual	Narrative	Word + attachments	Rev	E/P
Mechanical	Technical utilities PFD (fluid dedicated) - 1st issue for conceptual	Drawing	DWG	Rev	E/P
Mechanical	Technical utilities P&ID (fluid dedicated)	Drawing	DWG	Y	E/P

Mechanical	Technical utilities Piping Lay-Out - (for each level) / with details	Drawing	DWG	Y	E/P
Mechanical	Firefighting Lay-Out/Piping Layouts - Sections	Drawing	DWG	Y	E/P
Mechanical	Firefighting Material Requisition - MTO included	Specification	Word + Excel	Y	E/P
Mechanical	Typicals for piping Installation (non sanitary)	Drawing	DWG	Y	E/P
Mechanical	Mechanical Works Materials Requisition (non GMP systems) - MTO included	Specification	Word + Excel	Y	E/P
Mechanical	Piping classes Specification	Specification	Word	Y	E/P
Mechanical	Sanitary Piping Welding Specification	Specification	Word	Y	E/P
Mechanical	Technical utilities generation systems Data Sheet (chillers, towers, steam generators...)	Data sheets	Excel	Y	E/P
Mechanical	Technical utilities generation systems Specification (fluid dedicated)	Specification	Word	Y	E/P
Mechanical	Mechanical components technical specification (valves, painting, insulation...)	Specification	Word	Y	E/P
HVAC	HVAC systems Description - 1st issue for conceptual	Narrative	Word + attachments	Rev	E/P
HVAC	Detailed design criteria room by room (to be included in the conceptual for rev. 0)	Narrative and tables	Word + Excel	Rev	E/P
HVAC	Pressure Lay-Outs - 1st issue for conceptual	Drawing	DWG	Rev	E/P
HVAC	Area Classification Lay-Out - 1st issue for conceptual	Drawing	DWG	Rev	E/P
HVAC	HVAC flow diagram - 1st issue for conceptual	Drawing	DWG	Rev	E/P
HVAC	P&ID HVAC	Drawing	DWG	Y	E/P
HVAC	HVAC systems zoning - 1st issue for conceptual	Drawing	DWG	Rev	E/P
HVAC	Duct Oneline Lay-Out (for each level, planimetric distribution)	Drawing	DWG	Rev	E/P
HVAC	2D/3D Duct Lay-outs - with sections when required (for each level)	Drawing	DWG	Y	E/P
HVAC	HVAC Material requisition - MTO included. The chillers spec and data sheets will be included to the scope of HVAC contractor	Specification	Word + Excel	Y	E/P
HVAC	AHU Data Sheet	Data sheets	Excel	Y	E/P
HVAC	Re-Heating coils Data Sheet	Data sheets	Excel	Y	E/P
HVAC	AHU Specification	Specification	Word	Y	E/P
HVAC	Specification for HVAC Components (filters, diffusers, dumpers, etc)	Specification	Word	Y	E/P
HVAC	Ducts Specification	Specification	Word	Y	E/P
HVAC	Ducts insulation Specification	Specification	Word	Y	E/P
HVAC	Miscellaneus equipment for HVAC Specification	Specification	Word	Y	E/P
HVAC	Dedusting System Data sheet (where applicable)	Data sheets	Excel	Y	E/P
HVAC	Dedusting System Specification (where applicable)	Specification	Word	Y	E/P
HVAC	HVAC logical operation and sequences Specification	Specification	Word	Y	E/P
Electrical	Electrical systems description - 1st issue for conceptual	Narrative and attachments	Word	Rev	E/P
Electrical	Electrical Load List (by user and summary) - 1st issue for conceptual	Table	Excel	Rev	E/P
Electrical	Electrical plant Architecture / One line diagramme - 1st issue for conceptual	Drawing	DWG	Rev	E/P
Electrical	Elettrical Classification (ATEX) Technical Report	Specification	Word	Rev	E/P
Electrical	Electrical user points layouts - 1st issue for conceptual	Drawing	DWG	Rev	E/P
Electrical	Lighting levels calculations	Specification	Word + attachments	Y	E/P
Electrical	Detailed Lighting Lay-Out and switch positions (for each level)	Drawing	DWG	Y	E/P
Electrical	Emergency Lighting Lay-out (for each level)	Drawing	DWG	Y	E/P
Electrical	Motive Power detailed Lay-outs (for each level)	Drawing	DWG	Y	E/P
Electrical	Grounding network and lighting discharge Lay-out	Drawing	DWG	Y	E/P
Electrical	Data and telephone network Lay-out	Drawing	DWG	Y	E/P
Electrical	Interlocks and access control Lay-out (for each level)	Drawing	DWG	Y	E/P
Electrical	Fire fighting Lay-out (for each level)	Drawing	DWG	Y	E/P
Electrical	Antintrusion system Lay-out (for each level)	Drawing	DWG	Y	E/P
Electrical	CCTV layouts and systems description (for each level)	Narrative + attachments	Word + attachments	Y	
Electrical	Elettrical Plants Material Requisitions - MTO included	Specification	Word + Excel	Y	E/P
Electrical	Low currents systems Material Requisitions - MTO included	Specification	Word + Excel	Y	E/P
Electrical	Elettrical Board detailed wiring diagrammes	Drawing	DWG	Y	E/P
Electrical	Electrical Boards Data Sheets	Drawing	DWG	Y	E/P
Electrical	Electrical cable and cable trays layouts (for each level) / Cable trays designed also for instrument cables	Drawing	DWG	Y	E/P
Automation	I&C and Automation systems description - 1st issue for conceptual	Narrative + attachments	Word + attachments	Rev	E/P

Automation	Control and monitoring System Architecture (diagram and description) - 1st issue for conceptual	Narrative	Word	Rev	E/P
Automation	Facility Instrument List - HVAC systems	Table	Excel	Y	EP
Automation	Facility Instrument List - EMS systems	Table	Excel	Y	E/P
Automation	Facility Instrument List - Utilities Systems	Table	Excel	Y	E/P
Automation	Facility Instrument List - Process Utilities Systems	Table	Excel	Y	E/P
Automation	Facility Instrument List - Solution Preparation Systems	Table	Excel	Y	E/P
Automation	GMP systems (process and process utilities) instruments data sheets	Data sheets	Excel	Y	E/P
Automation	BMS and HVAC Control and monitoring System Specification	Specification	Word	Y	E/P
Automation	EMS Control and monitoring System Specification	Specification	Word	Y	E/P
Automation	Process Control and monitoring System Specification	Specification	Word	Y	E/P
Automation	Instrument Cable layouts	Drawing	DWG	Y	E/P
Automation	BMS, HVAC and utilities control Systems Material Requisition- MTO included	Specification	Word + Excel	Y	E/P
Automation	EMS Material Requisition - MTO included	Specification	Word + Excel	Y	E/P
Automation	PMS (Particle Monitoring System) Material Requisition - MTO included	Specification	Word + Excel	Y	E/P
Automation	BMS, PMS, EMS functional sequences and logics	Specification	Word	Y	E/P

Overview of the list of User Requirements Specifications (URS) required to be developed and approved as part of the conceptual and baseline design

1. Primary User Requirements Specifications (URS)

Document containing a set of requirements for the building, all areas included in the conceptual and baseline design, critical auxiliary systems i.e.

- HVAC including hot water and chilled water and Chillers,
- UDAF,
- condensate,
- WFI water,
- process gases, i.e. compressed air, nitrogen,
- clean steam,
- main computerized systems being expanded as part of the investment task (i.e. RMS, BMS, PMS)
- toxic and non-toxic wastewater discharge system,
- access control system,
- CCTV,
- UPS,
- PLC,
- electrical system.

2. User Requirements Specifications (URS) for processing equipment:

- insulator for weighing
- solution preparation system – (SUS) and filtration set-up
- autoclaves;
- VHP chamber;
- automatic parts washer;
- filling line (vials/PFS/cartridges);
- balances;
- isolated transport system;
- decontamination shower (MS);