PEAK BIOTECH

Production Chromatography System Requirements Checklist

Purpose

Use this checklist to provide the key process, system and facility information needed for an initial evaluation of your production chromatography requirements. The information allows Peak Biotech to establish a preliminary system configuration and prepare a budgetary quotation based on the required flow, pressure, process functionality and production environment. Final equipment specifications are defined later in the project based on the approved URS and detailed engineering requirements.

Project information

Project name	
Company / site	
Contact person	
Product / application	GLP 1, peptide or other application
Required production capacity	Batch requirement, campaign requirement or other available capacity basis
Target equipment delivery	

1. Process flow and pressure

These parameters define the hydraulic capacity and pressure range the chromatography system has to support.

Requirement	Notes	Project info
Required flow rate	Provide the process flow or flow range where available.	Min L/h Max L/h or cm/h
Required operating pressure	Defines the pressure the system must support during the chromatography process.	bar
Maximum system pressure (if specified)	Provide the required maximum pressure if already defined.	☐ 6 bar ☐ 10 bar ☐ 20 bar ☐ 30 bar ☐ 80 bar ☐ Other:
Chromatography operation	Defines whether the system needs to mix mobile phases during the process.	☐ Gradient ☐ Isocratic ☐ Both ☐ To be reviewed

2. Buffers and solvents

The mobile phases and their supply conditions are needed to define the inlet configuration, wet materials and solvent handling requirements.

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Requirement	Notes	Project info
Buffers / solvents	List all relevant process buffers and solvents, including concentrations where known.	
Number of buffer / solvent inlets	Defines the required inlet manifold configuration.	_____ inlets ☐ To be reviewed
Buffer / solvent supply	Defines the inlet pressure conditions for system design.	☐ Open / atmospheric tank ☐ Pressurized supply: _____ bar ☐ Other: _____
Cleaning chemistry	List cleaning agents, concentrations and contact time where known.	_____

3. Process measurements and detection

Required process measurements define the instrumentation and control functions included in the preliminary system configuration.

Requirement	Notes	Project info
Measurements before column	Select measurements required upstream of the column.	☐ Pressure ☐ Temperature ☐ pH ☐ Conductivity ☐ Other:
Measurements after column	Select measurements required downstream of the column and for product detection.	☐ UV ☐ Pressure ☐ Flow ☐ Conductivity ☐ Temperature ☐ pH ☐ Other:
Gradient control / feedback	Relevant when the process requires gradient monitoring or control.	☐ Conductivity ☐ NIR ☐ Flow ☐ Density ☐ Other: ☐ To be reviewed
Flow measurement	Provide preferred measurement principle if already specified.	☐ Mass flow ☐ Magnetic flow ☐ To be reviewed ☐ Other:

4. Product collection and process functions

These functions define how the system handles product, waste and supporting process operations.

Requirement	Notes	Project info
Product / fraction outlets	Number of product fractions or outlet destinations required.	_____ product / fraction outlets _____ waste outlets
CIP manifold	For connection and routing of cleaning solutions.	☐ Required ☐ To be reviewed ☐ N/A
Additional process functions	Select functions already known to be required.	☐ Sample loop ☐ Heat exchanger ☐ Filter ☐ N_2 blowing of fraction lines ☐ Valve feedback ☐ Other:

5. Process contact materials

Process and cleaning chemistry are used to define suitable wet materials, seals and surface finish.

Requirement	Notes	Project info
Product contact material	SS316L is the standard starting point.	☐ SS316L ☐ Other:
Sealing material	Final selection follows process chemistry and system configuration.	☐ PTFE ☐ EPDM ☐ Other: ☐ To be reviewed
Product contact surface roughness	Provide project requirement if specified.	☐ Ra < 0.8 µm ☐ Ra < 0.6 µm ☐ Other: _____ ☐ To be reviewed

6. Facility, utilities and regulatory requirements

Facility interfaces are inputs to the system configuration, including available space, utilities, access and hazardous area requirements.

Requirement	Notes	Project info
Available equipment space	Is there a restriction in the process area into which we should design the equipment?	L _____ mm W _____ mm H _____ mm
Access restrictions	Restrictions in access to the process room?	Door / corridor / handling limits:
Power supply	Provide site power where known.	
Available air supply	Provide available instrument air pressure and connection where known.	☐ 6 bar ☐ Other: bar Connection:
Hazardous area classification		☐ No Ex ☐ ATEX Zone 2 ☐ ATEX Zone 1 ☐ Class I Div II ☐ Other:
Other laws / regulations		

7. Control, automation and GMP requirements

Automation and compliance requirements define the control architecture and documentation scope to be considered in the budgetary quotation.

Requirement	Notes	Project info
System operation	Define preferred operator interface if known.	☐ Local operation panel ☐ Other: _____ ☐ To be reviewed
GAMP requirement		☐ Yes ☐ No ☐ To be defined
GMP / validated application		☐ Yes ☐ No ☐ To be defined
Site automation / communication requirements	List required interface or communication standard if known.	

8. Documentation and project scope

Requirement	Notes	Project info
Required documentation / qualification	Examples may include material documentation, welding traceability, FAT, SAT, IQ/OQ support or project specific documentation.	
Third party inspection requirement	Provide requirement if already defined.	☐ Yes ☐ No ☐ To be defined
Other project requirements		
Expected quotation timing		
Expected equipment delivery timing		

Open questions for Peak engineering review