PEAK BIOTECH

Production Chromatography Column Requirements Checklist

Purpose
Use this checklist to provide the key process, column and facility information needed for an initial evaluation of your production chromatography requirements. The information allows Peak Biotech to establish a preliminary column configuration and prepare a budgetary quotation based on the required production scale and chromatography conditions. 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	
Required production capacity	
Target equipment delivery	

1. Packed bed and chromatography media

These parameters establish the required bed geometry and connect the chromatography method with the physical column configuration.

Requirement	Notes	Project info
Internal column diameter	Enter defined diameter of the column size of interest.	mm
Packed bed length	Define target bed height or required operating range.	Min mm Max mm
Column volume (if known)	Relevant to column size	L
Slurry volume (if known)	Relevant to slurry volume	L
Packing media/ resin type		☐ Silica ☐ Polymer ☐ Agarose ☐ Other:
Particle size	Nominal particle size or range.	µm
Frit pore size	Select in relation to the chromatography media.	☐ 2 µm ☐ 5 µm ☐ 10 µm ☐ 20 µm ☐ 30 µm ☐ Other:

2. Flow, pressure and temperature

Flow and pressure requirements define the hydraulic and mechanical conditions the column has to support.

Requirement	Notes	Project info
Column design flow rate	Provide volumetric flow and/or linear velocity where available.	L/h or cm/h
Column design / maximum packing pressure	Confirm normal process pressure separately if known.	☐ 6 bar ☐ 10 bar ☐ 20 bar ☐ 30 bar ☐ 100 bar ☐ Other:
Expected normal operating pressure		bar
Working temperature	Standard range shown for initial project definition.	☐ 0–50 °C ☐ Other:

3. Process chemistry and product contact materials

The complete process and cleaning chemistry should be considered when product contact materials and seals are specified.

Requirement	Notes	Project info
Process solvents / buffers	List all relevant solvents, buffers and concentrations.	
Cleaning chemistry	List all cleaning agents, contact time and concentrations where known.	
Column material	SS316L is the standard starting point.	☐ SS316L ☐ Other:
Sealing material	Final selection follows column platform and process chemistry.	☐ PTFE ☐ PEHD ☐ EPDM ☐ Other:
Class VI elastomer requirement		☐ Yes ☐ No ☐ To be defined
Product contact surface roughness		☐ Ra < 0.8 µm ☐ Ra < 0.6 µm ☐ Other:

4. Packing, unpacking and supporting equipment

Packing and unpacking are part of the production workflow and should be considered while the column configuration is being defined.

Requirement	Notes	Project info
Slurry inlet valve	Recommended for larger columns and slurry volumes.	☐ Required ☐ To be reviewed
Slurry outlet valve	Not applicable for all media types. Resins packed with high pressure cannot be emptied using the outlet valve	☐ Required ☐ To be reviewed ☐ N/A
Slurry preparation unit		☐ Required ☐ To be reviewed ☐ N/A

5. Facility, utilities and regulatory requirements

Facility interfaces are engineering inputs to the equipment configuration, including available space, access, utilities and applicable pressure or 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 the access to the process room?	Door / corridor / handling limits:
Available air supply	Feed line / connection:	☐ 6 bar ☐ Other: bar
Hazardous area classification		☐ No Ex ☐ ATEX Zone 2 ☐ ATEX Zone 1 ☐ Other:
Pressure approval code		☐ PED ☐ ASME ☐ Other:
Other laws / regulations		
Frame material	SS304 is the standard starting point.	☐ SS304 ☐ Other:

6. Documentation and project scope

Requirement	Notes / open points	Project value / selection
Required documentation / qualification	Examples may include material documentation, FAT, SAT, IQ/OQ support or project specific documentation.	
Expected quotation timing		
Expected equipment delivery timing		
Other project requirements		

Open questions for Peak engineering review