



Peak Biotech - Company & Product Presentation



Peak Biotech Company Profile

July 2005 Peak Biotech A/S was founded

Location Kvistgaard, Denmark

Jacob Nøhr QA Manager (founder)

Kim Vind Managing Director (founder)

Both with many years of experience in delivering equipment to the pharmaceuticals and Biotech industry, also from their earlier jobs.

Peak Biotech A/S
Porthusvej 7A
3490 Kvistgaard
Denmark
Tel. +45 70 276 279
www.peakbiotech.com



Peak Biotech Chromatography Products



Chromatography columns

Low pressure DAC columns 3 / 6 / 10 bar
Medium pressure DAC columns 20 / 30 bar
High pressure DAC columns 70 / 100 bar

Fix bed and mechanically compression versions available for all pressure ranges

Chromatography systems

Low pressure gradient systems 6 / 10 bar
Medium pressure gradient systems 20 / 30 bar
High pressure gradient systems 80 bar

Systems are also available in step or isocratic versions

Slurry handling equipment

Slurry units for soft media
Slurry units for hard silica media



Peak Biotech - Other Products / Accessories

Handling equipment

Piston handling equipment for service & maintenance of columns

Bottom handling equipment

Compression units

For low and medium pressure columns

Ultra sonic bath

For cleaning of frits with dimensions up to $\varnothing 1200$

Tanks

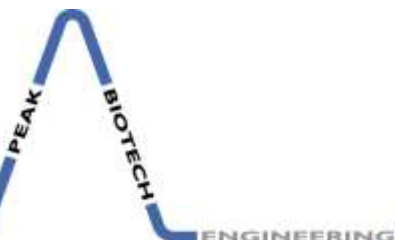
Mobile tanks 1 - 500 L

Stationary tanks 1 - 3000 L

Buffer systems

Buffer systems with preparation and storage tanks

In-line buffer preparation systems



Chromatography columns - low & medium pressure

Specifications

- Diameters from 100 – 1600 mm
- Low pressure DAC columns 3 / 6 / 10 bar
- Medium pressure DAC columns 20 / 30 bar
- Slurry inlet valve
- Slurry outlet valve
- Sealing materials PEHD, PTFE & PEEK
- Materials of construction 1.4404, 1.4435, SS316L, SAF2205
- Construction code PED or ASME

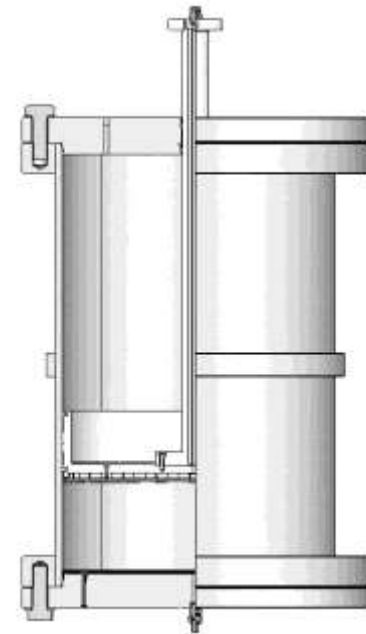
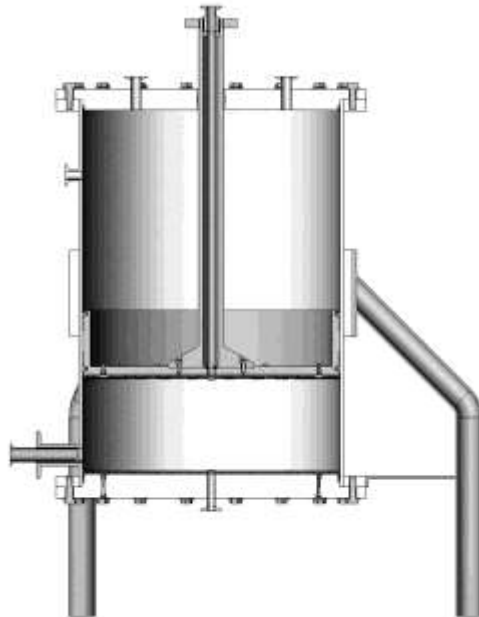
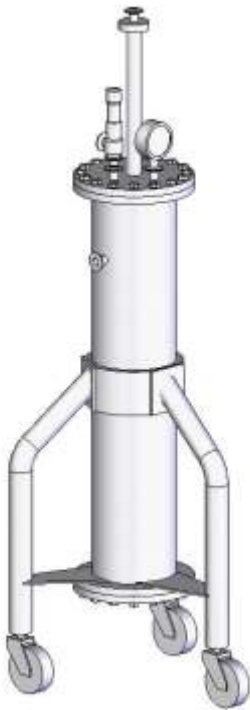
Options

- Isolated
- Cooling / heating jacket
- USP Class VI approved sealing material
- ATEX approved (for use in explosion proof areas)



Key features

- Easy packing through slurry inlet valve
- Easy packing through slurry outlet valve
- Uniform distribution system
- High performance and reproducibility
- Leak detection system
- No sealing adjustment
- Scalable
- Mobile construction



Accessory : Slurry Unit for Soft Gel Media



Chromatography Columns - high pressure

Specifications

- Diameters from 50 – 1000 mm
- Pressure DAC columns 100 bar
- Sealing materials PTFE & PEEK
- Material of construction 1.4404, 1.4435, SS316L, SAF2205
- Construction code PED or ASME

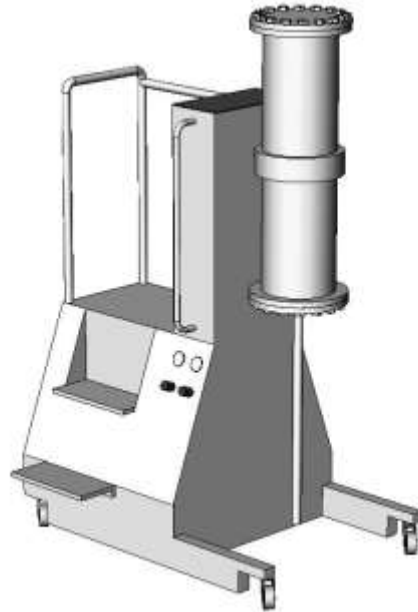
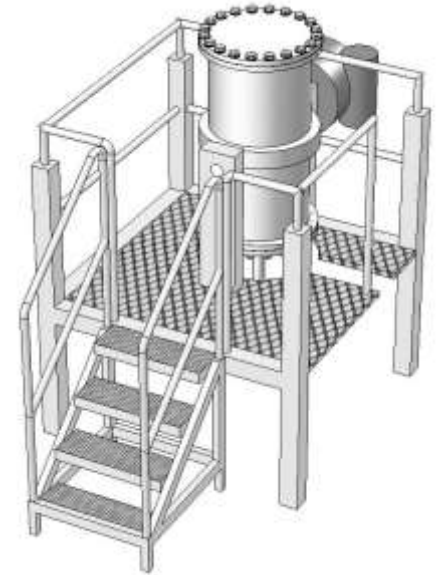
Options

- Column slurry valve
- Cooling heating / jacket
- USP Class VI approved sealing material
- ATEX approved (for use in explosion proof areas)



Key features

- Easy packing and unpacking
- Uniform distribution system
- Removable frit design for easy cleaning or replacement
- High performance and reproducibility
- Leak detection system
- No sealing adjustment
- Scalable
- Mobile construction up to 300 mm
- Ergonomic working positions



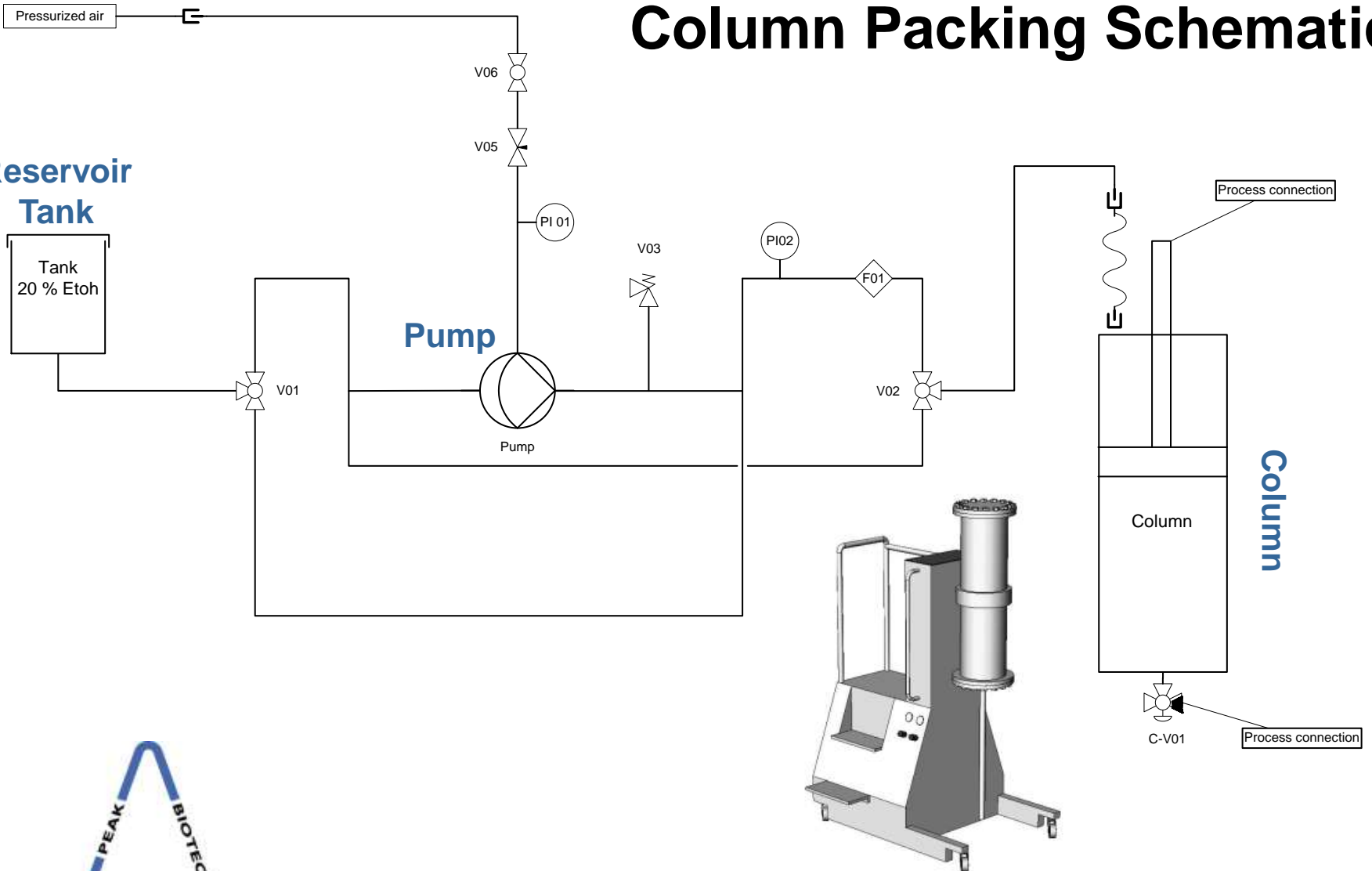
Accessory : Slurry Unit for Silica Media



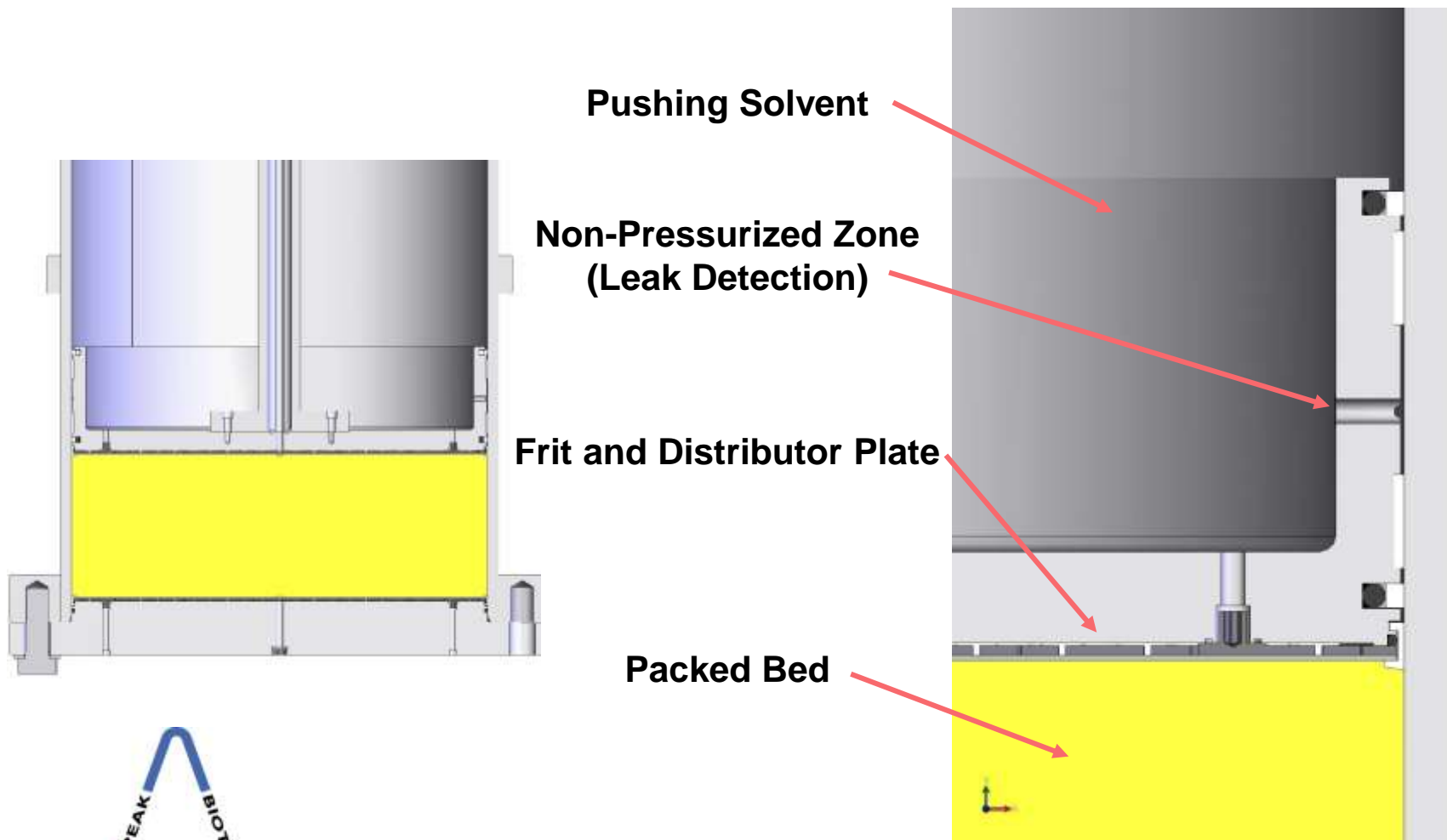
Pressurized Air Feed

Column Packing Schematic

Reservoir Tank

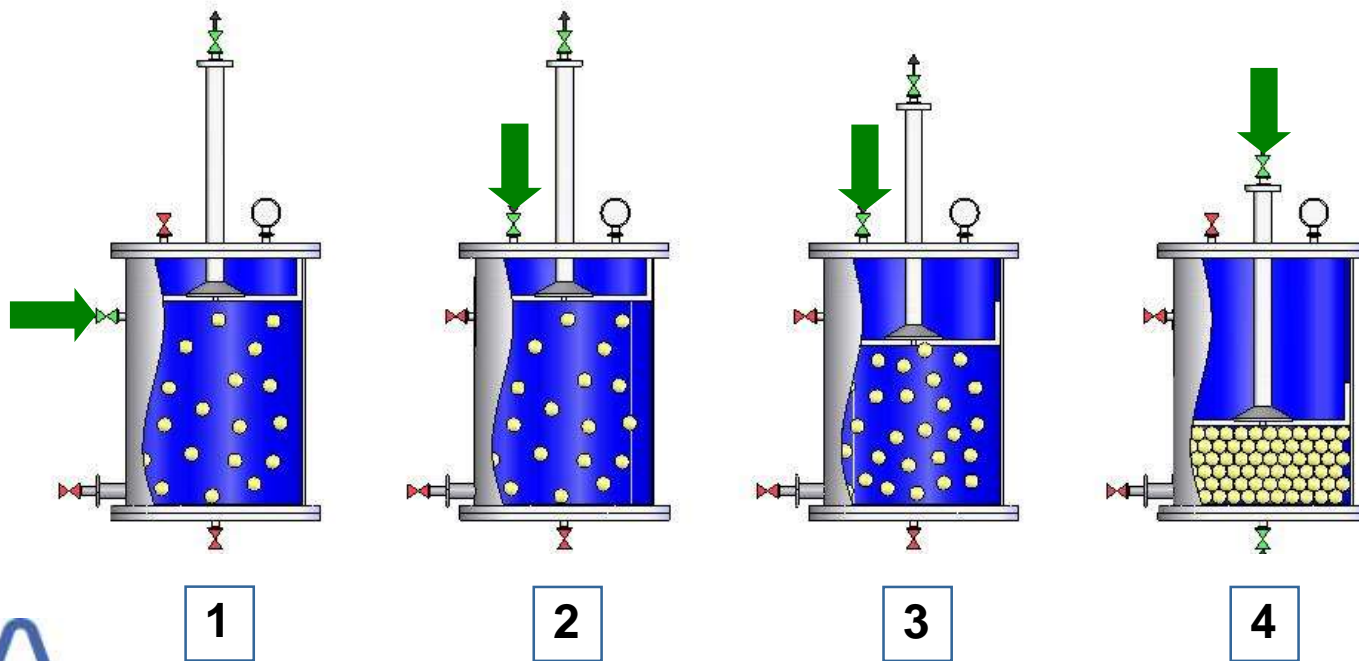


LC Column – Cross Section View



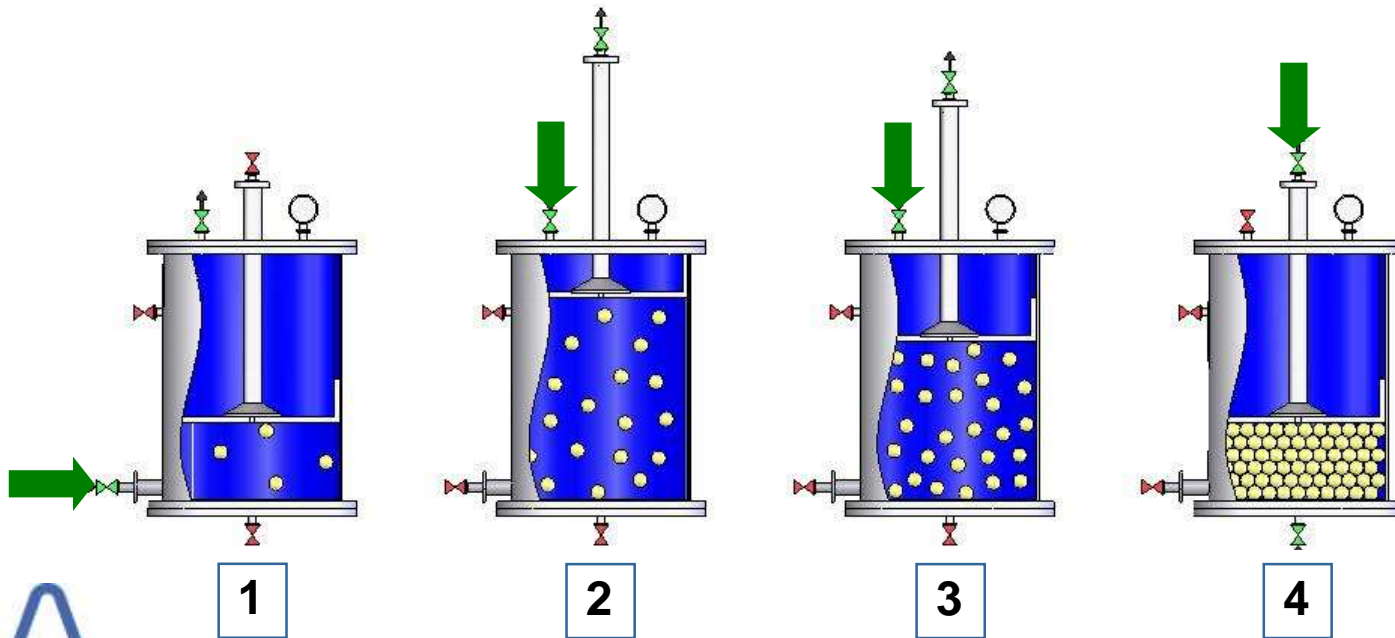
Column Packing *Using Slurry Inlet Valve*

- 1 – slurry pumped into the column
- 2 – piston pressurized & column packed
- 3 – column packing in progress
- 4 – column ready for LC use



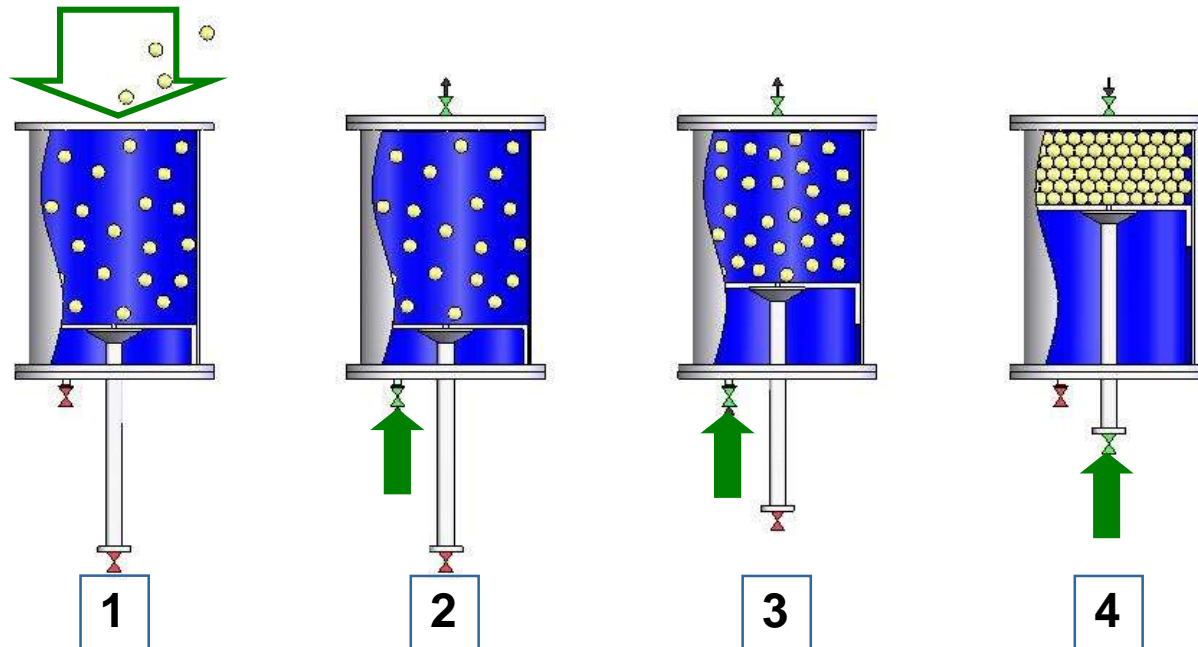
Column Packing *Using Slurry Outlet Valve*

- 1 – slurry loaded into the column (suction)
- 2 – piston pressurized & column packed
- 3 – column packing in progress
- 4 – column ready for LC use



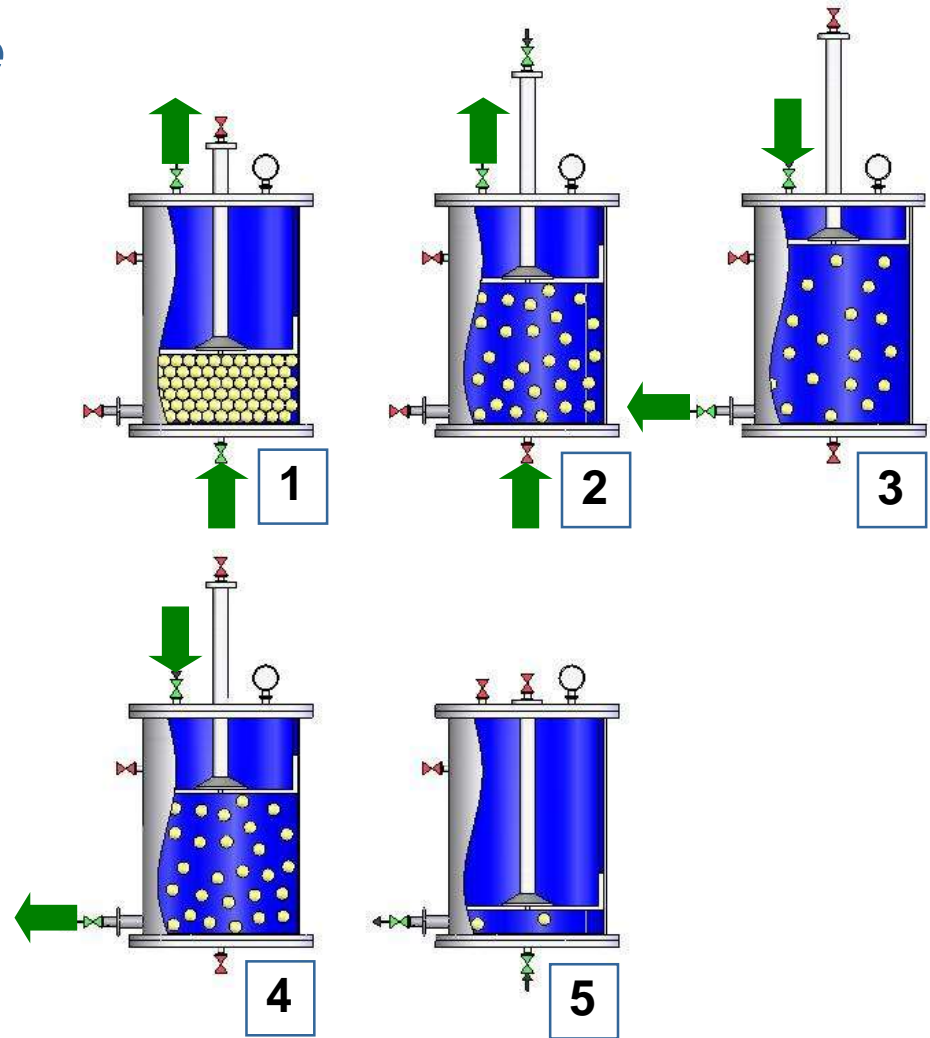
Column Packing *Loading Through Outlet Flange*

- 1 – load slurry into the open column
- 2 – close flange & pressurize piston
- 3 – column packing in progress
- 4 – column ready for LC use



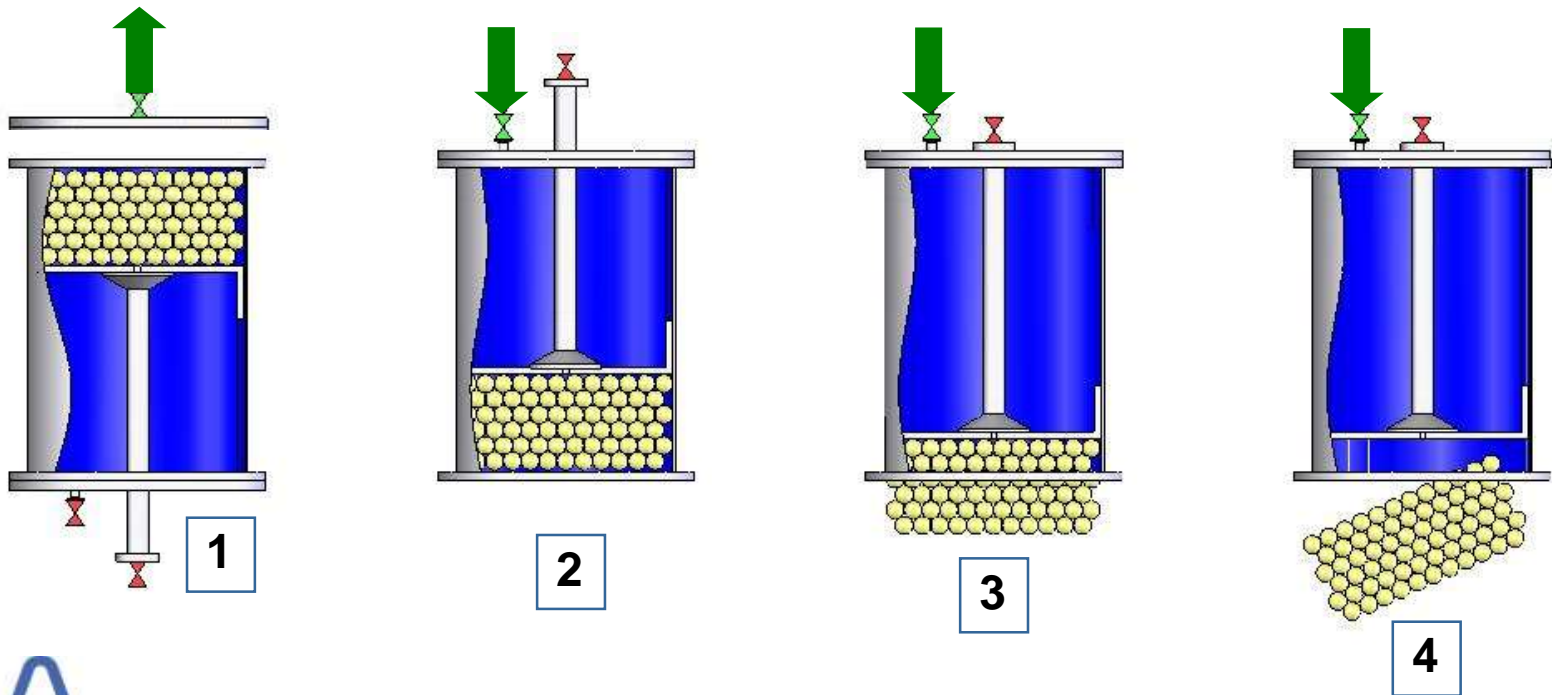
Column Un-Packing Through Slurry Outlet Valve (works only for Soft-gel media)

- 1 – retract piston & draw solvent in
- 2 – re-slurry the packing bed
- 3 – pressurize / lower piston again
- 4 – pump the re-slurried media out
- 5 – column ready for next packing



Column Un-Packing *Through Outlet Flange*

- 1 – remove the outlet flange
- 2 – turn column & pressurize piston
- 3 – column un-packing in progress
- 4 – column bed pushed out



Chromatography Systems - low pressure

Specifications

- Flow rates 6 – 5000 l/h
- Pressure rates 0 – 6 bar
- Gradient loop with feedback for conductivity sensor
- 4 Buffer inlets, 1 product and 5 fractions
- Sealing materials PTFE or EPDM
- Material of construction 1.4404, 1.4435, SS316L

Options

- ATEX / Class One div 2 (for use in explosion proof areas)
- Extra inlets and outlets
- Extra instrumentation before and after the column
- Recycle option
- Filter module in-line
- Heat exchanger
- Sample / Injection loop
- Nitrogen blowing of product lines

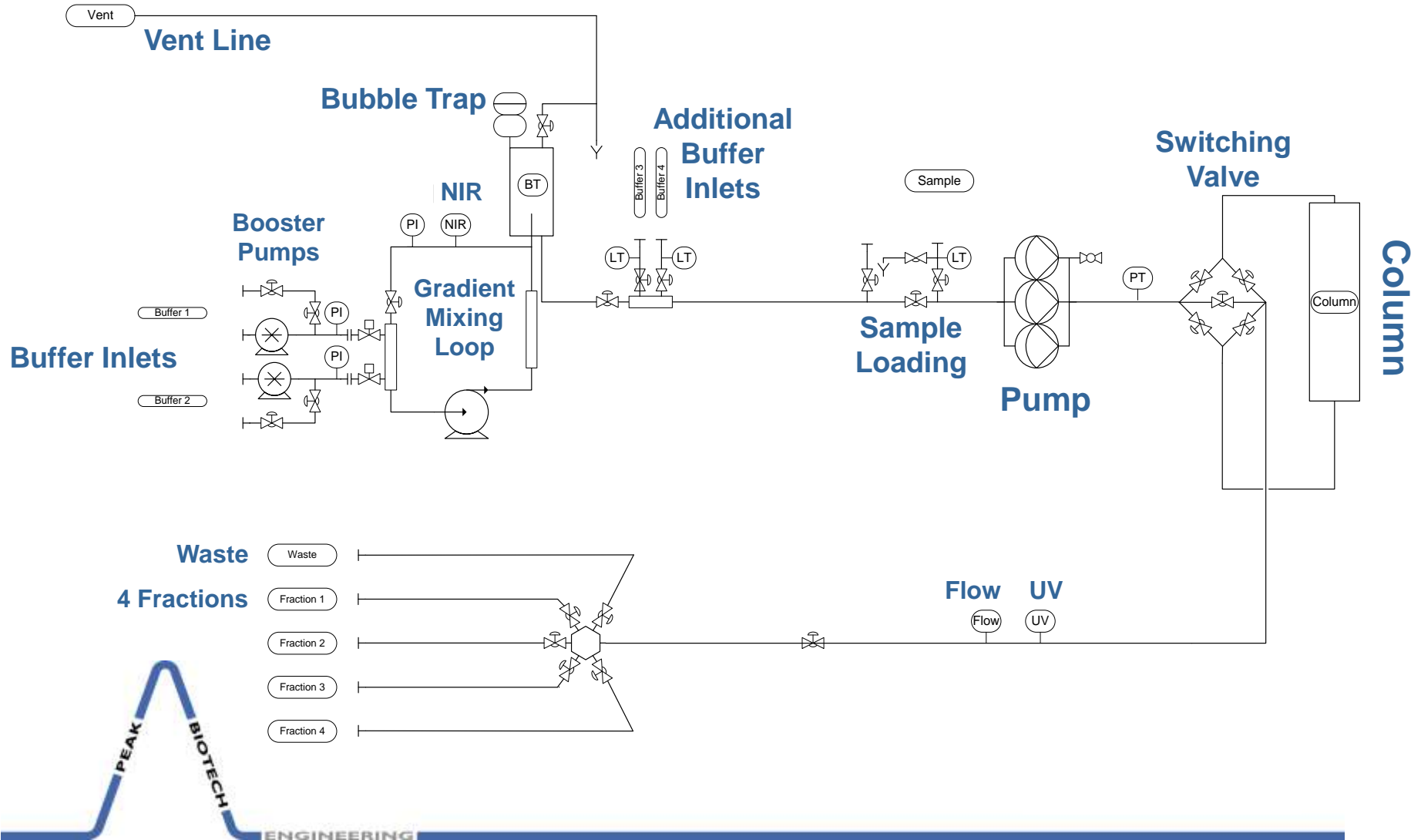


Key features

- Gradient performance with high accuracy
- Fully automated, CFR Part 11 and GAMP 4 compliant
- Mobile construction
- Complete unit, tested and documented
- Compact and reliable
- Flexible control
- Easy maintenance
- Sanitary design



Typical Chromatography systems - low pressure



Chromatography systems - medium and high pressure

Specifications

- Flow rates 6 – 5000 l/h for medium pressure
- Flow rates 6 – 1000 l/h for high pressure
- Pressure rates 0 – 20 bar & 0 - 80 bar
- Gradient loop with feedback for NIR, mass or conductivity
- 4 Buffer inlets, 1 product and 5 fractions
- Sealing material PTFE
- Material of construction 1.4404, 1.4435, SS316L

Options

- ATEX / Class One div 2 (for use in explosion proof areas)
- Extra inlets and outlets
- Extra instrumentation before and after the column
- Recycle option
- Filter module in-line
- Heat exchanger
- Sample / Injection loop
- Nitrogen blowing of product lines

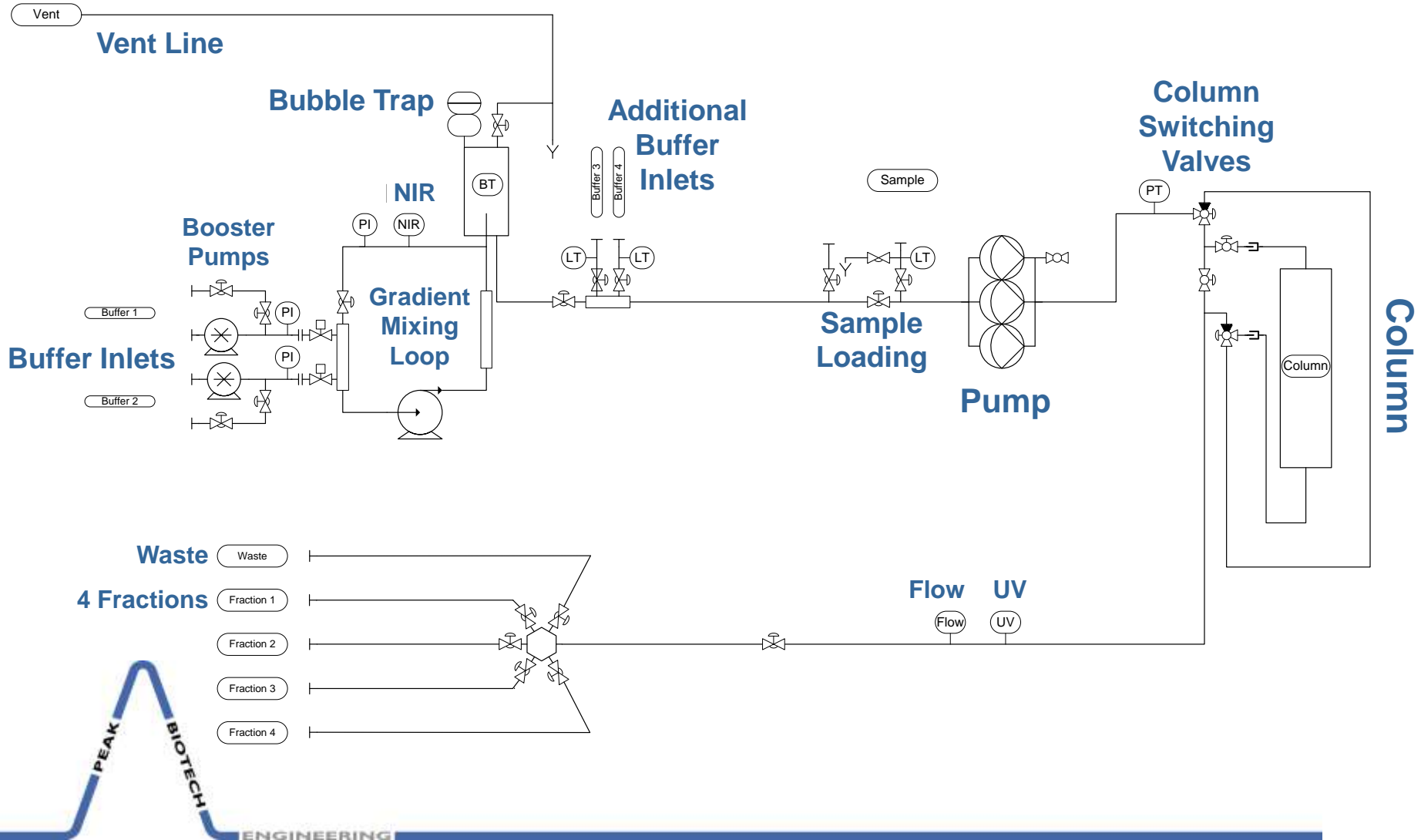


Key features

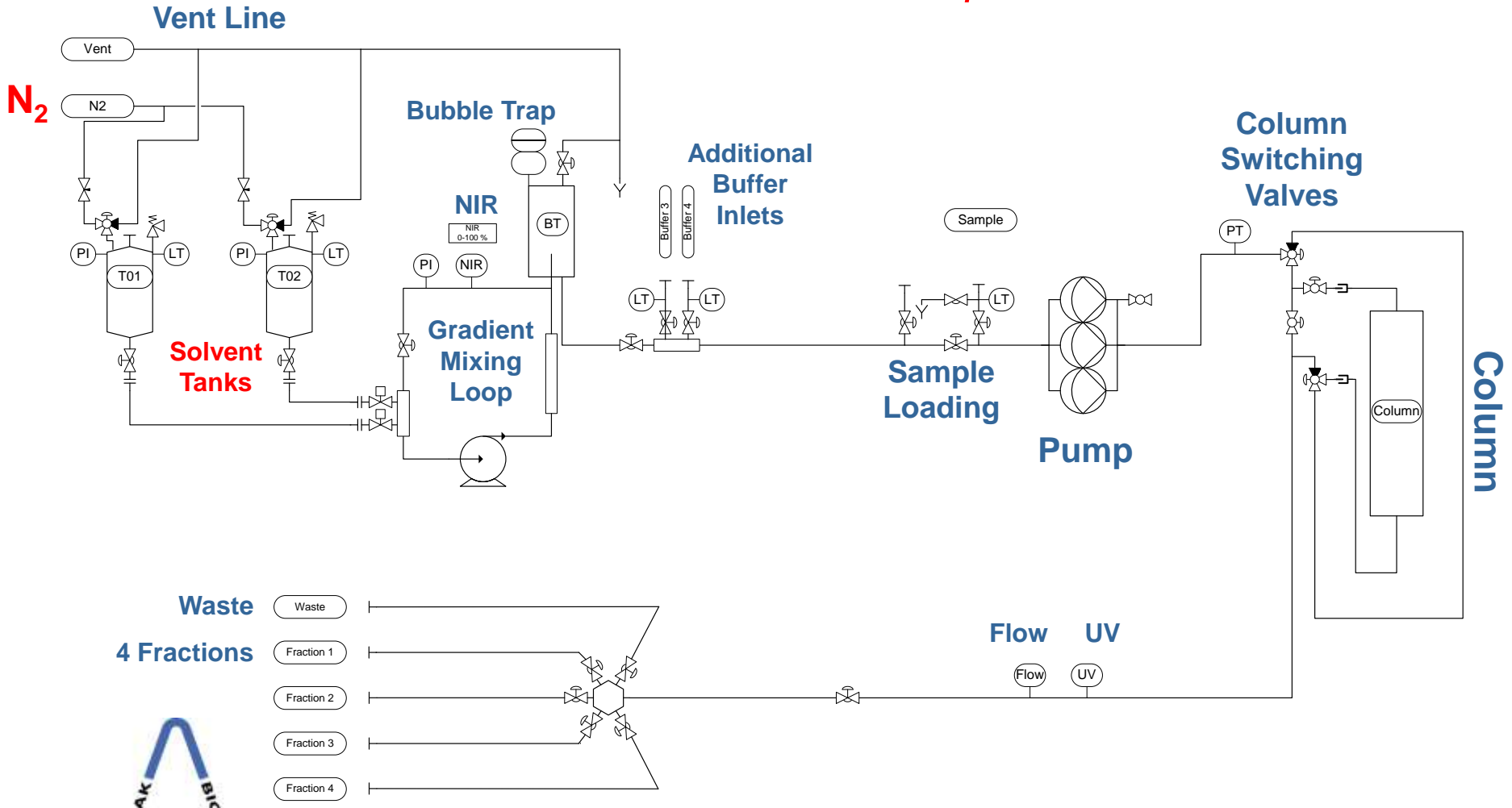
- Gradient performance with high accuracy
- Fully automated, CFR Part 11 and GAMP 4 compliant
- Mobile construction
- Complete unit, tested and documented
- Compact and reliable
- Flexible control
- Easy maintenance
- Sanitary design



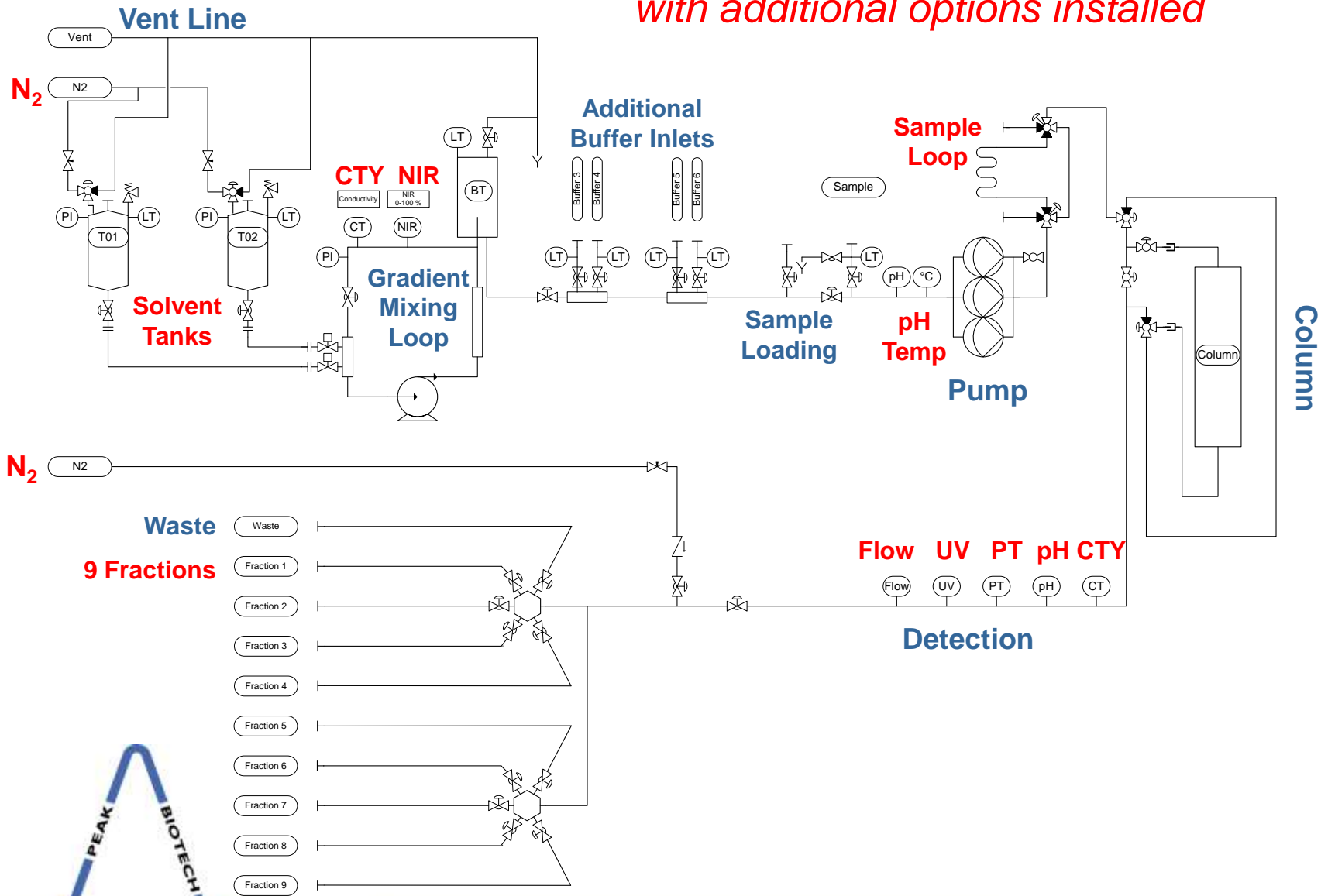
Typical Chromatography System - medium & high pressure



Chromatography System - medium & high pressure *with additional options installed*



Chromatography System - medium & high pressure *with additional options installed*

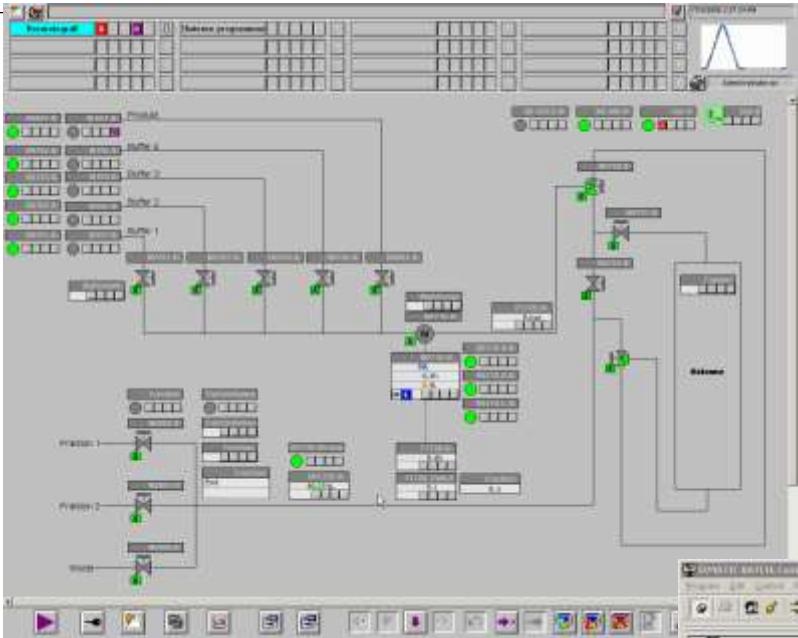


Peak Control Software

Key Features

- Based on Siemens PCS 7
- Fully automated
- CFR Part 11 compliant
- GAMP 4 compliant
- Programmed according to S88 standard
- Fully tested and validated
- Flexible control





Peak Control Software

A screenshot of the Peak Control Software interface. The left pane shows a file tree with folders like 'Library', 'Pilot room', 'Forevald', 'A32', 'Column', 'WPC', 'Template 200x700', 'Orders', 'Method test', '11872084', 'A32', '4520test', 'Customer ABC', 'Fullflowtest', 'KV Test 10002006', '2006-06-16 PE (the test)', 'Main Batch.cu?', 'test3', and 'Pilotlab'. The main area displays two process flow diagrams. The first diagram, titled '10062006 test02', shows a sequence: Start -> Flow system -> EQ 01 -> Product load -> Elution -> End. The second diagram, titled 'Product load', shows a sequence: Start -> Flow system -> Run & Flow start -> End. The interface includes a toolbar at the top and a status bar at the bottom.

Peak Control Software

The image displays three screenshots of the Peak Control Software interface, illustrating different process flow diagrams and a list of triggers.

Top Left Screenshot: KV 10072006 - V1.1 [in progress]

This screenshot shows a vertical flow diagram with the following components: Start, Prime system, EQ 01, Load, and End. A context menu is open over the 'Prime system' block, listing the following actions and shortcuts:

- Open object: Ctrl+Alt+O
- Cut: Ctrl+X
- Copy: Ctrl+C
- Paste: Ctrl+V
- Delete: Del
- abc Add comment ...
- Resolve substructure
- Hide in substructure
- Properties ...: Alt+Return

Top Right Screenshot: Recipe 001 - V1.1 [in progress]

This screenshot shows a vertical flow diagram with the following components: Start, three 'FracQueue' blocks, and End. A list of triggers is displayed to the right of the diagram:

Fractions trigger:

- Time
- Volume
- CV
- UV pos. slope
- UV neg. slope
- UV Peak
- UV Valley
- % of peak
- UV value

Bottom Screenshot: Recipe 001 - V1.1 [in progress]

This screenshot shows a horizontal flow diagram with the following components: Start, Buffer inlet t01, Main pump t01, Column t01, Fraction t01, and End. The flow is indicated by arrows connecting these components in sequence.

Questions / Comments ?

