

## The principle of MCSGP on the Contichrom™ platform

*Continuous Chromatography for Biologics*

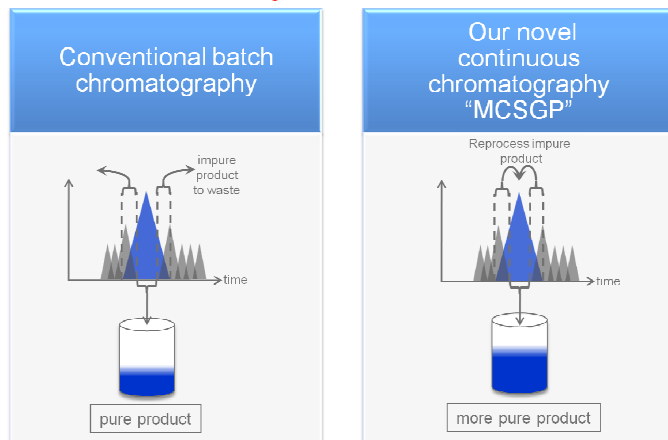
### Batch chromatography

- is an established, discontinuous separation process (pulsed feed)
- its aim is to separate the biopharmaceutical target product and its impurities
- the components are fractionated due to the different affinities of the components to the resin

### Limitations of batch chromatography

- often a complete isolation is not achieved
- product-rich side fractions which do not have the required purity need to be discharged (see figure below)
- wasting of target product is very expensive since the target product is highly valuable

## The Principle: recycle until it's pure



### Principle of the MCSGP process

- it is a continuous chromatographic process
- the MCSGP process recycles impure side fraction inside the process until they are pure
- this leads to more pure product as shown on the right hand side of the above figure
- MCSGP can employ any mobile/stationary phase combination used in batch chromatography

### Unique features of MCSGP on the Contichrom™ equipment platform

- performance increase (compared to batch chromatography):
  - 50% higher yield and purity
  - 10-fold increase in throughput
  - 70% less buffer consumption
- the MCSGP process on the Contichrom™ equipment platform is easily scalable
- it enables the use of high pressures and low particle sizes in production scale. These features support further the intrinsic high resolution power of the MCSGP

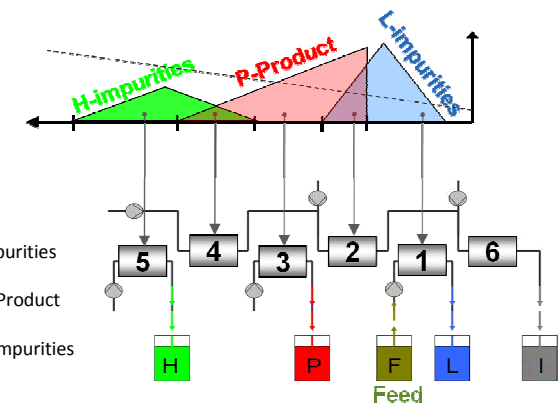


## The principle of MCSGP on the Contichrom™ platform (continued)

### Detailed technical description of the MCSGP principle

The flowsheet shows six columns, where each column inlet is either connected to a pump (columns 5, 3, 1) or to the mixed stream of previous column outlet and a pump (columns 4, 2, 6). Each task which needs to be performed in the batch chromatogram is also executed in the MCSGP. The tasks are the following:

### Chromatogram with reversed time axis



### Task of column number:

1. load Feed & elute L-Impurities
2. elute overlapping Product/L-Impurities
3. elute Product
4. elute overlapping H-impurities/Product
5. elute H-impurities, CIP
6. receive overlapping Product/L-Impurities

After a fixed time period (a few minutes), the columns are switched one position to the left and column 5 becomes column 6.

### Number of columns

While the MCSGP principle as explained above is based on 6 columns, the hardware implementation generally uses 2 or 3 columns in order to reduce the number of equipment components. This can be achieved since in the principle above, there is 1 flowsheet with 6 columns. Instead, 2 alternating flowsheets with 3 columns can be used or 3 alternating flowsheets with 2 columns.

### Animated process principle

For more explanations and animation of the process, please refer to [www.chromacon.ch](http://www.chromacon.ch).

### Equipment

The Contichrom™ equipment platform has been optimized for the operation of the MCSGP process, please refer to [www.chromacon.ch](http://www.chromacon.ch) for more details.

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