Claims

What is claimed is:

1) A method of monitoring three or more chromatography columns being operated in continuous process mode for efficiency and quality, the method comprising:

    a) providing three or more chromatography columns used in a series in continuous mode, with one column performing a non-loading step;

    b) detecting changes during the non-loading step, in one or more process parameters selected from the group consisting of pH, conductivity, salt concentration, light absorption, fluorescence after excitation with light of a suitable wavelength, refractive index, electrochemical response and mass spectrometry immediately before, during and directly after the exchange of one process fluid to another process fluid that differ in the one or more process parameters to generate process data;

    c) applying a curve smoothing filter, comprising a moving average generated with inqual weight per data point, to said process data to generate corrected process data;

    d) calculating the first derivative of said corrected process data to produce derivatized process data of said corrected process data;

    e) determine the Height of Theoretical Plate, HETP, value and asymmetry of said derivatized data;

    f) comparing the HETP value and asymmetry to standardized values;

    g) wherein, if the HETP values and asymmetry fall within said standardized values the column is used for another process run.

2) The method of Claim 1, wherein said curve smoothing calculation is the Savitzky-Golay smoothing filter.

3) The method of Claims 1 or 2, wherein said column or columns have been used continuously for between 2 and 200 runs.

4) The method of Claim 3, wherein said column or columns have been used continuously for between 5 and 50 runs.

5) The method of any of Claims 1 – 4, wherein said continuous process mode comprises at least three but not more than five different columns in sequence.

6) The method of any of Claims 1 – 5, wherein said columns are selected from the group consisting of affinity, ion exchange, size exclusion, reverse phase, chiral, frontal and hydrophobic.

7) The method of any of Claims 1 – 6, wherein each column is monitored for efficiency and quality.

8) The method of any of Claims 1 – 7, wherein said continuous process mode comprises multiple process steps, comprises at least three but not more than ten process steps in sequence and at least one process step comprises a chromatography column.

9) The method of any of Claims 1 – 8, wherein said standardized values are based on historic data using the same or substantially the same columns and process parameters.

10) The method of any of Claims 1 – 9, wherein if the HETP values and asymmetry do not fall within said standardized values the column is regenerated.

11) The method of any of Claims 1 – 10, wherein if the HETP values and asymmetry do not fall within said standardized values an operator is notified by an automatic system.