CLAIMS

1. A process control method, comprising:

generating smoothed data by applying a noise reduction technique to raw chromatography data, wherein the noise reduction technique comprises using a smoothing filter on a portion of raw chromatography data to generate smoothed data;

generating processed chromatography data by selecting smoothed data matching a feature of a chromatogram transition;

performing a transition analysis to generate transition data; and

performing an action based on the transition data, wherein performing the action includes generating a notification of an event, generating an evaluation of the event, or generating a deviation notification form.

2. The method of claim 1, wherein the feature of the chromatogram transition includes:

a derivative duration;

a maximum intensity;

a duration from initiation; or

expected background noise.

3. The method of claim 1, wherein the noise reduction technique further includes selecting the portion of the raw chromatography data using predetermined set points.

4. The method of claim 1, wherein the noise reduction technique further includes:

analyzing the portion of raw chromatography data for dynamic signal errors;

normalizing the portion of raw chromatography data to prevent magnitude bias; or both.

5. The method of claim 1, wherein performing the transition analysis includes:

generating a performance parameter based on the processed chromatography data, the performance parameter including a maximum rate of change, a number of inflection points, a breakthrough volume, a cumulative error, a curve asymmetry, or a combination thereof; and

generating transition data based on the performance parameter or generating transition data based on the performance parameter in combination with historical data.

6. The method of claim 1, wherein performing a transition analysis includes:

generating a curve using the processed chromatography data;

analyzing the curve to generate a performance parameter; and

generating the transition data based on the performance parameter.

7. A process control method, comprising:

processing raw chromatography data including a plurality of signals and a plurality of blocks, to generate processed raw chromatography data by applying a noise reduction technique to the plurality of signals and the plurality of blocks;

performing a transition analysis on the processed raw chromatography data, to generate transition data, wherein performing the transition analysis includes:

generating a curve using the processed chromatography data;

analyzing the curve to generate a performance parameter; and

generating the transition data based on the performance parameter; and

performing an action based on the transition data, wherein performing the action includes generating a notification of an event, generating an evaluation of the event, or generating a deviation notification form.

8. The method of claim 7, further comprising:

generating an Individual chart, Moving Range chart, or Range chart; and

applying a statistical process control to the Individual chart, Moving Range chart, or Range chart, to generate performance data.

9. The method of claim 8, wherein performing the action based on the transition data includes performing the action based on the transition data and the performance data.

10. The method of claim 7, wherein each signal of the plurality of signals is associated with one of a plurality of blocks, and

wherein each block of the plurality of blocks corresponds to a step in the chromatography column run.

11. The method of claim 7, wherein processing raw chromatography data includes selecting a combination of a first block and a first signal from the raw chromatography data.

12. The method of claim 11, wherein selecting the combination of the first block and the first signal includes selecting the combination according to a profile defining a plurality of selection criteria, wherein the plurality of selection criteria comprises one or more of:

whether blocks occur at regular chromatography cycle intervals;

an extent to which one of the plurality of signals saturates a detector;

an extent to which the plurality of signals approaches a stationary phase at a distinct level;

a magnitude of variation in the plurality of signals; and

a number of inflection points shown by the plurality of signals during a transition phase.

13. The method of claim 7, wherein the performance parameter includes two or more of:

a maximum rate of change;

a number of inflection points;

a breakthrough volume;

a cumulative error;

a curve asymmetry; and

a height equivalent of a theoretical plate.

14. The method of claim 7, further comprising performing a chromatography column run and generating the raw chromatography data from the chromatography column run.

15. The method of claim 14, wherein the transition data is indicative of an integrity of a chromatography column used in the chromatography column run.

16. The method of claim 7, further comprising:

generating smoothed data by applying the noise reduction technique to a selection of the raw chromatography data, wherein the noise reduction technique increases a signal-to-noise ratio of the selection of the raw chromatography data; and

processing raw chromatography data includes processing the smoothed data.

17. A process control method, comprising:

generating smoothed data by applying a noise reduction technique to raw chromatography data, wherein the noise reduction technique comprises:

selecting a portion of raw chromatography data using predetermined set points; and

using a smoothing filter on the portion of raw chromatography data to generate smoothed data;

generating a performance parameter based on the smoothed data, wherein the performance parameter includes:

a maximum rate of change;

a number of inflection points;

a breakthrough volume;

a cumulative error;

a curve asymmetry;

a height equivalent of a theoretical plate; or

a combination thereof;

generating transition data based on the performance parameter; and

performing an action based on the transition data, wherein performing an action includes generating a notification of an event, generating an evaluation of the event, or generating a deviation notification form.

18. The method of claim 17, wherein the noise reduction technique further comprises normalizing the selected portion of data to prevent magnitude bias and analyzing the selected portion of data for dynamic signal errors.

19. The method of claim 17, further comprising:

performing a chromatography column run, wherein the raw chromatography data is generated during the chromatography column run; and

wherein the transition data is indicative of an integrity of a chromatography column used in the chromatography column run.

20. The method of claim 17, wherein generating the performance parameter includes:

generating a curve using the smoothed data; and

analyzing the curve to generate the performance parameter.

21. A process control method, comprising:

receiving raw chromatography data including a plurality of signals and a plurality of blocks;

processing the raw chromatography data by selecting a combination of a first block and a first signal from the raw chromatography data;

performing a transition analysis on the processed raw chromatography data, wherein performing the transition analysis includes:

generating performance parameters, the performance parameters including a maximum rate of change or a number of inflection points; and

based on the performance parameters, generating the transition data;

generating an Individual chart, a Moving Range chart, or a Range chart based on the transition data; and

generating performance data by applying a statistical process control to the Individual chart, Moving Range chart, or Range chart.

22. The process of claim 21, further comprising performing an action based on the performance data, wherein the action comprises at least one of:

generating a notification of an event;

generating an evaluation of the event; or

generating a deviation notification form.

23. The method of claim 21, further comprising performing a chromatography column run and generating raw chromatography data from the chromatography column run;

wherein the raw chromatography data is used to generate the processed chromatography data.

24. The method of claim 23, wherein the raw chromatography data includes a plurality of signals, and each signal of the plurality of signals is associated with one of a plurality of blocks, and

wherein each block of the plurality of blocks corresponds to a step in the chromatography column run.

25. The method of claim 23, further comprising:

generating smoothed data by applying a noise reduction technique to a selection of the raw chromatography data, wherein the noise reduction technique increases a signal-to-noise ratio of the selection of the raw chromatography data.

26. The method of claim 25, further comprising:

generating the processed chromatography data by selecting smoothed data matching a feature of a chromatogram transition.

27. The method of claim 25, wherein performing the noise reduction technique includes:

selecting a portion of the raw chromatography data to analyze using predetermined set points;

using at least one smoothing filter on the selected portion of data to generate smoothed data;

normalizing the selected portion of data to prevent magnitude bias; and

analyzing the selected portion of data for dynamic signal errors.

28. The method of claim 21, wherein the transition analysis further includes:

generating a curve using the processed chromatography data; and

analyzing the curve to generate performances parameters.

29. A process control method, comprising:

receiving a selection of raw chromatography data;

generating smoothed data by applying a noise reduction technique to the selection of raw chromatography data, wherein the noise reduction technique comprises:

selecting a portion of the raw chromatography data to analyze using predetermined set points; and

using at least one smoothing filter on the selected portion of data to generate smoothed data;

generating processed chromatography data by selecting smoothed data matching a feature of a chromatogram transition, wherein the feature of the chromatogram transition includes:

a derivative duration;

a maximum intensity;

a duration from initiation; or

expected background noise; and

using the processed chromatography data to generate one of an Individual chart, a Moving Range chart, or a Range chart.

30. The method of claim 29, wherein the noise reduction technique further comprises:

normalizing the portion of raw chromatography data to prevent magnitude bias;

analyzing the portion of raw chromatography data for dynamic signal errors; or

both.

31. The method of claim 29, further comprising:

generating performance data by applying a statistical process control to the Individual chart, Moving Range chart, or Range chart by:

performing a multivariate data analysis; or

performing a principal component analysis.

32. The method of claim 31, further comprising:

performing an action based on the performance data, wherein the action comprises at least one of:

generating a notification of an event;

generating an evaluation of the event; or

generating a deviation notification form.

33. The method of claim 29, wherein the selection of raw chromatography data is received from a chromatography process skid.

34. The method of claim 29, further comprising:

performing a transition analysis on the processed chromatography data to generate transition data, wherein performing the transition analysis includes:

generating performance parameters, the performance parameters including a maximum rate of change or a number of inflection points; and

based on the performance parameters, generating the transition data; and

performing an action based on the transition data, wherein performing the action includes generating a notification of an event, generating an evaluation of the event, or generating a deviation notification form.

35. The method of claim 29, further comprising:

performing a transition analysis to generate transition data, wherein performing a transition analysis includes:

generating a curve using the processed chromatography data;

analyzing the curve to generate performance parameters; and

based on the performance parameters, generating the transition data; and

performing an action based on the transition data, wherein performing the action includes generating a notification of an event, generating an evaluation of the event, or generating a deviation notification form.

36. A process control method, comprising:

receiving raw chromatography data including a plurality of signals, wherein each signal of the plurality of signals is associated with one of a plurality of blocks;

generating processed chromatography data by applying a noise reduction technique to a subset of the raw chromatography data, wherein applying the noise reduction technique includes:

selecting a portion of the subset of the raw chromatography data to analyze using predetermined set points; and

using at least one smoothing filter on the portion to generate smoothed data;

generating performance parameters, the performance parameters including a maximum rate of change or a number of inflection points;

based on the performance parameters, generating the transition data; and

performing an action based on the transition data, wherein performing the action includes generating a notification of an event, generating an evaluation of the event, or generating a deviation notification form.

37. The method of claim 36, further comprising:

performing a chromatography column run, wherein the raw chromatography data is received from the chromatography column run.

38. The method of claim 36, wherein each block of the plurality of blocks corresponds to a step in a chromatography process.

39. The method of claim 36, further comprising:

selecting the combination of the first block and the first signal according to a profile defining a plurality of selection criteria, wherein the plurality of selection criteria comprises:

whether blocks occur at regular chromatography cycle intervals;

an extent to which one of the plurality of signals saturates a detector;

an extent to which the plurality of signals approaches a stationary phase at a distinct level;

a magnitude of variation in the plurality of signals; or

a number of inflection points shown by the plurality of signals during a transition phase, and

wherein the subset of data is obtained from the combination of the first block and the first signal.

40. The method of claim 36, further comprising:

generating an Individual chart, a Moving Range chart, or a Range chart based on the transition data; and

generating performance data by applying a statistical process control to the Individual chart, Moving Range chart, or Range chart,

wherein performing the action based on the transition data includes performing the action based on the performance data.