



Internal quality control in a high throughput laboratory

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Agenda

- Defining a series of analyses
- Planning
- Daily interpretation
- Periodic review

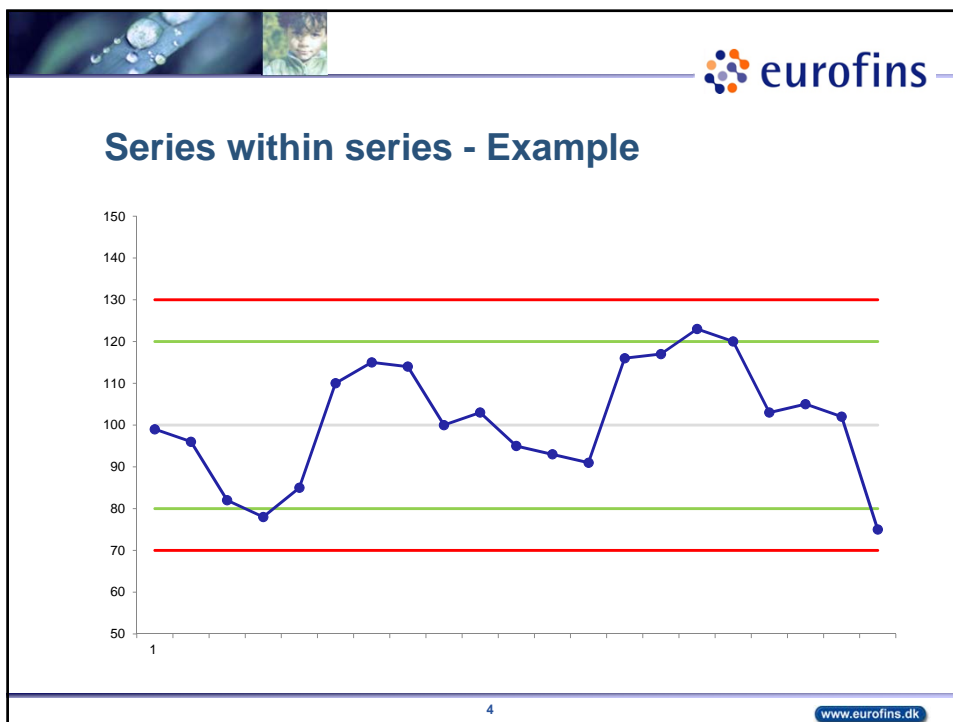
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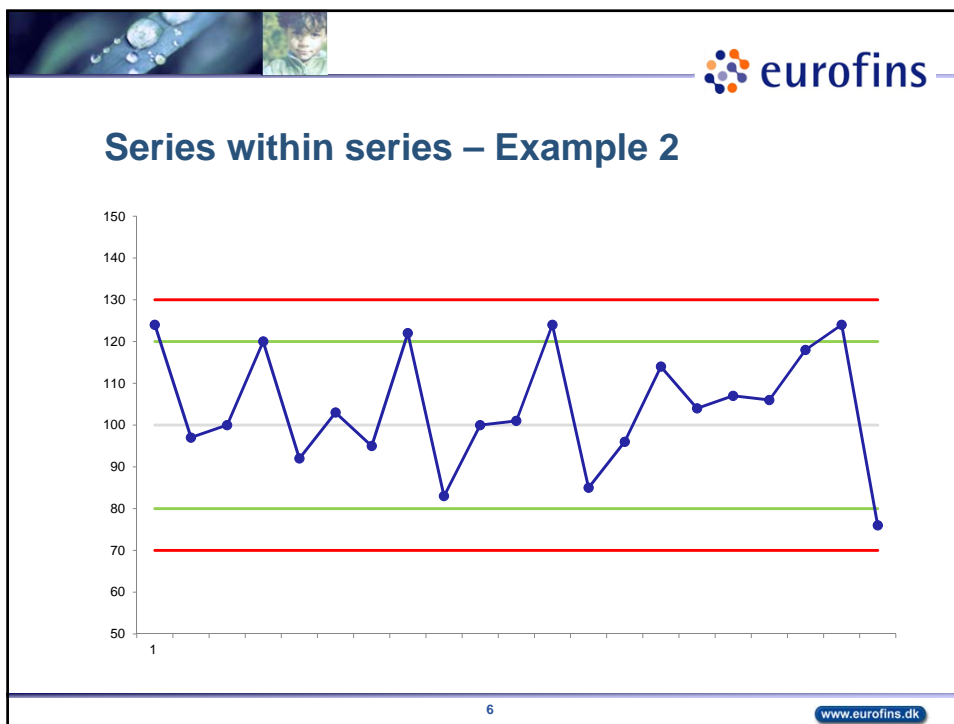
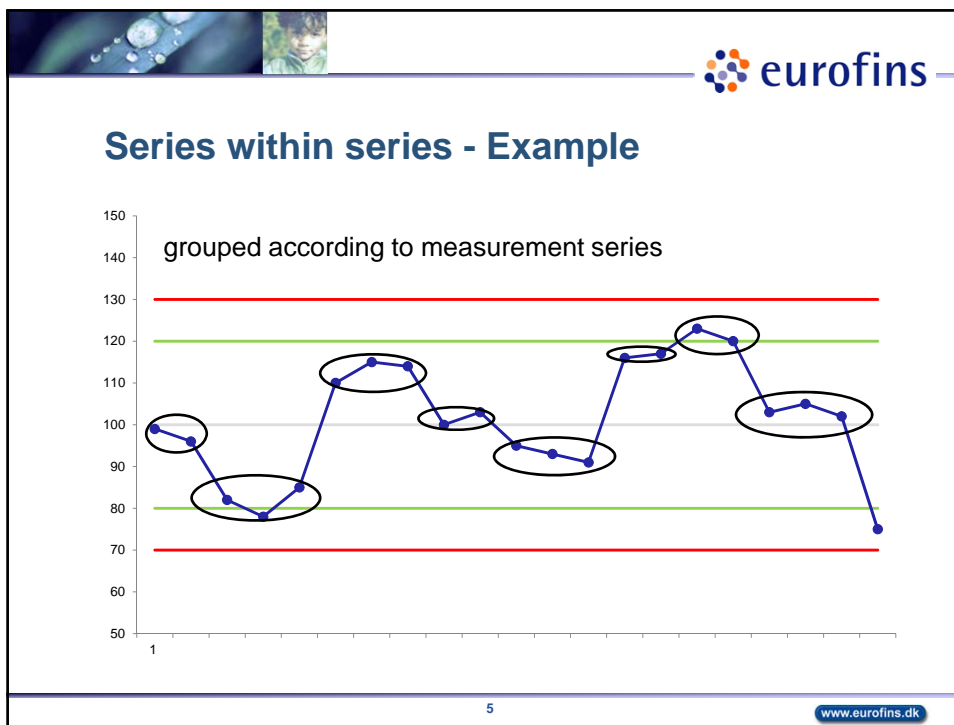


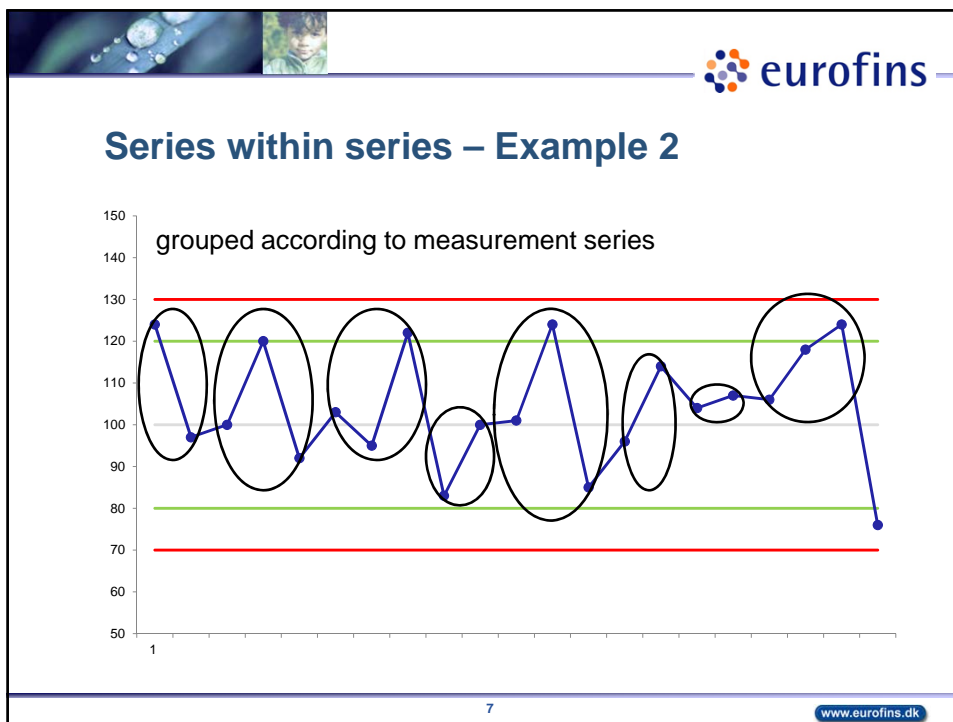
Defining a series of analyses

- **One measurement may be part of two or more series:**
 - a pre-treatment series, e.g. preservation, grinding
 - a preparation series, e.g. digestion, extraction
 - a measurement series, e.g. ICP, HLPC
- This consideration is relevant for most laboratories

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The graph displays a blue line series with data points connected by lines. The y-axis ranges from 50 to 150. The x-axis is labeled with '1' at the first point and '7' at the seventh point. The series exhibits a cyclical pattern with several peaks and troughs. Several segments of the series are circled in black, indicating sub-series. Horizontal reference lines are drawn across the graph: two red lines at approximately y=130 and y=70, and two green lines at approximately y=120 and y=80. The text 'grouped according to measurement series' is positioned above the graph.

150
140
130
120
110
100
90
80
70
60
50



grouped according to measurement series

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Defining a series of analyses



- **Where does one series stop and a new begin? For example:**
 - When the equipment is turned off and turned on again
 - When the equipment is recalibrated
 - When reagents are changed
 - When a new shift starts
 -



Planning of QC

- Principles as for every laboratory:
 - plan concentrations and types of control samples according to the scope of the laboratory's method
 - define purpose of each control: whole method, part of method (e.g. control of calibration drift)
 - control at the beginning and end of each series
 - intermediate checks to suit the stability of the measurement process, stability of samples, and the cost associated with repeated measurement
 - define what goes into database for generation of update on general quality of analyses



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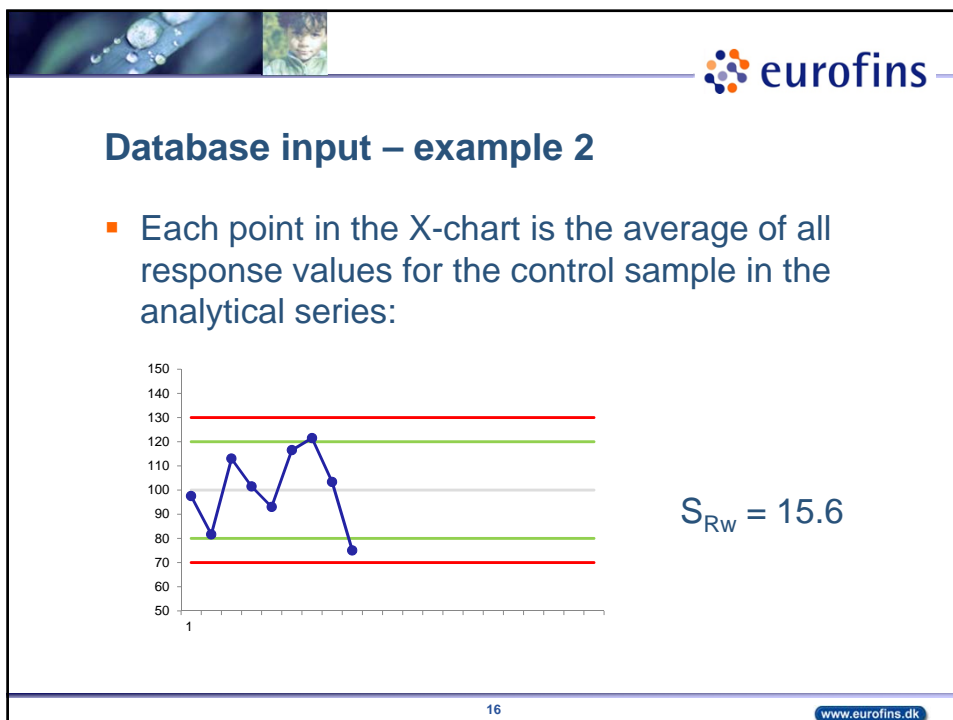
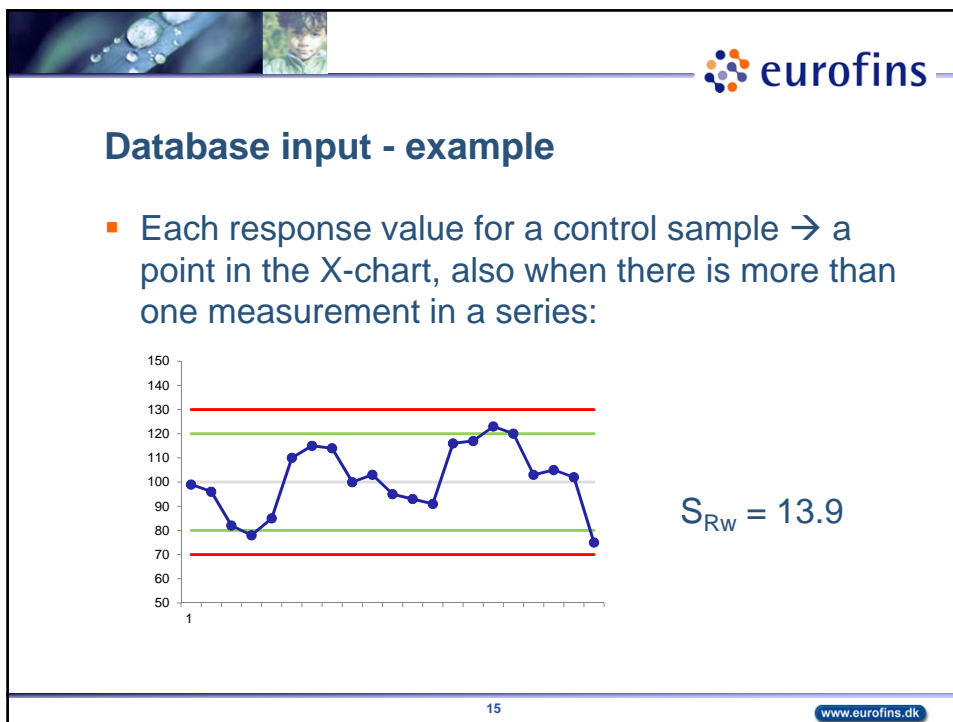
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Input to database

- Only one point on an X-chart or D-chart for one series of analyses for charts intended as input to general quality of analysis.
- No restrictions for charts not intended for general quality of analysis

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Daily interpretation

- Principles as for every laboratory:
 - define out-of-control situations
 - define responsibility for corrections
 - define responsibility for resuming work
 - by default: stop analyses and do not report results, unless person in charge takes action


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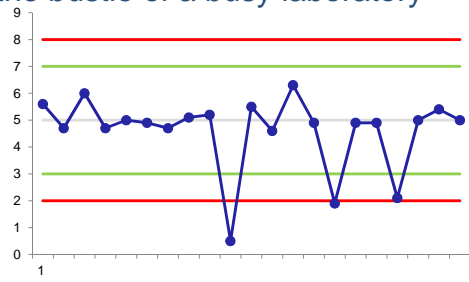
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Analyses stopped unless action is taken

- Action must be taken in out-of-control situations
 - usually an initiative is taken when this occurs
 - in automated, (semi-)continuous systems there is a risk that an out-of-control situation is overlooked or neglected in the bustle of a busy laboratory



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Analyses stopped unless action is taken

- Action must be taken in out-of-control situations
 - usually an initiative is taken when this occurs
 - in automated, (semi-)continuous systems there is a risk that an out-of-control situation is overlooked or neglected in the bustle of a busy laboratory
 - therefore **LIMS systems should prevent data since last in-control from being reported** unless the person responsible actively allows continuation

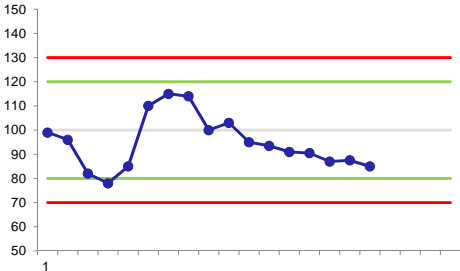
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Periodic review


- Principles as for every laboratory, look for
 - Trends




The graph shows a blue line with circular markers representing data points over 21 intervals. The y-axis ranges from 50 to 150. Horizontal control lines are drawn at 70 (red), 80 (green), 100 (grey), 120 (green), and 130 (red). The data points start at approximately 100, drop to a low of about 80, rise to a peak of about 115, and then gradually decline towards the 70 control line.

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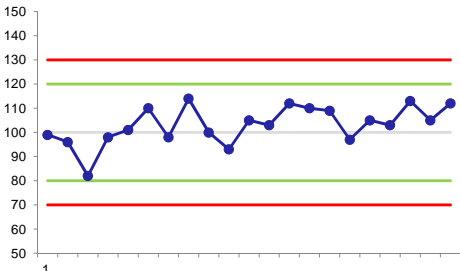
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Periodic review


- Principles as for every laboratory, look for
 - Trends
 - Shifts




The graph shows a blue line with circular markers representing data points over 22 intervals. The y-axis ranges from 50 to 150. Horizontal control lines are drawn at 70 (red), 80 (green), 100 (grey), 120 (green), and 130 (red). The data points fluctuate around a mean value of approximately 100, with several points touching the 80 and 120 control lines.

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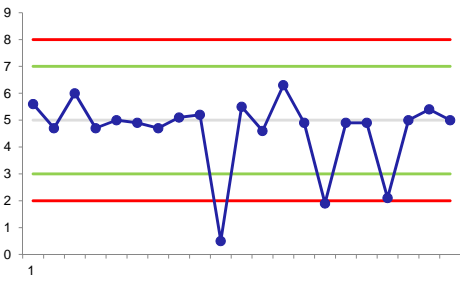
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Periodic review


- Principles as for every laboratory, look for
 - Trends
 - Shifts
 - Frequency of out-of-control situations



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Periodic review

- Principles as for every laboratory, look for
 - Trends
 - Shifts
 - Frequency of out of control situations
 - General quality of analysis

One of the inputs for measurement uncertainty (within laboratory reproducibility, bias) and limit of quantification. Do the newest data still support the labs' specifications?

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Summary

- IQC for large series of automated analyses works according to the same principles as for every laboratory
- High throughput laboratories should give special attention to
 - defining an analytical series
 - intermediate checks and associated action
 - input to database of control data – no mixing of within and between series controls
 - automatic block on reporting in out-of-control situations
 - focus on periodic review

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