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Internal quality control
in a high throughput laboratory
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1
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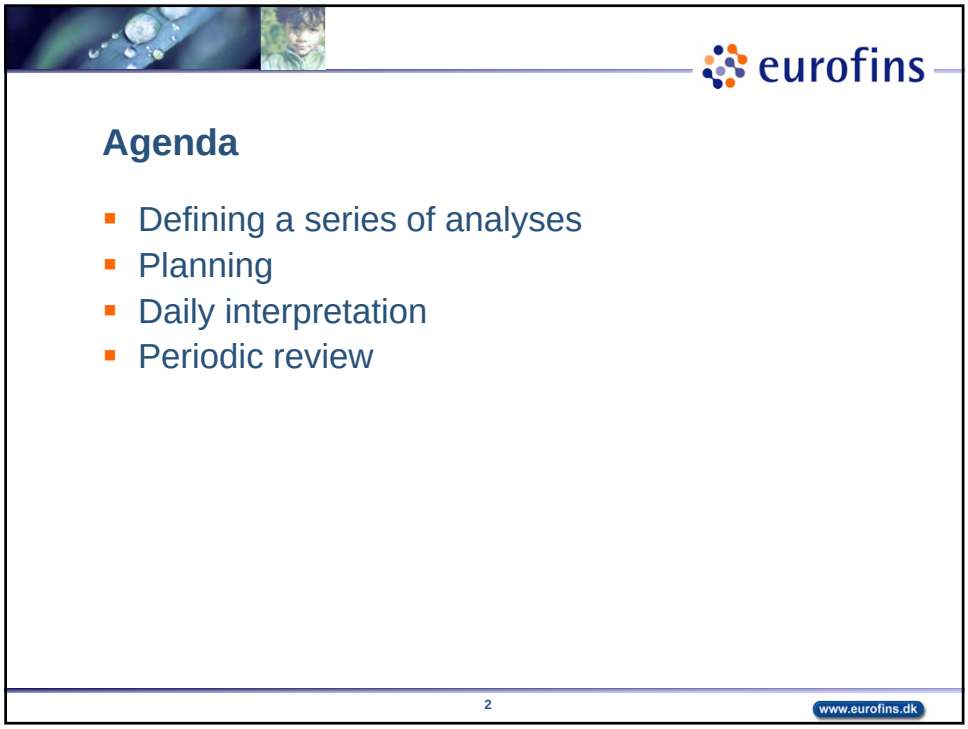
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Agenda
Defining a series of analyses
Planning
Daily interpretation
Periodic review
2
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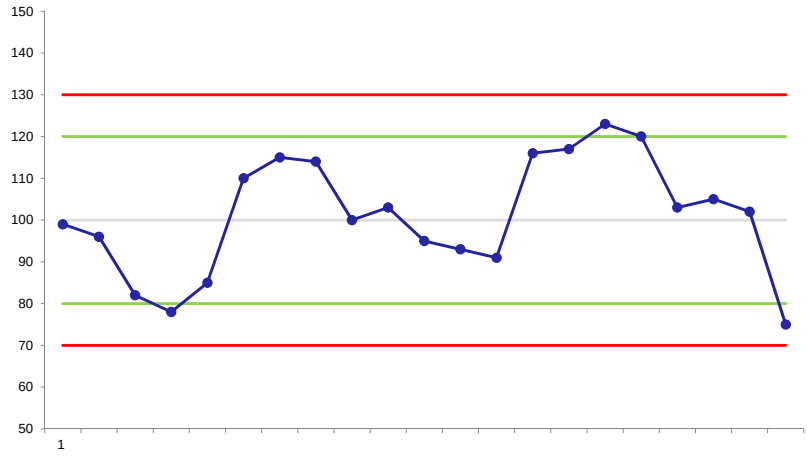
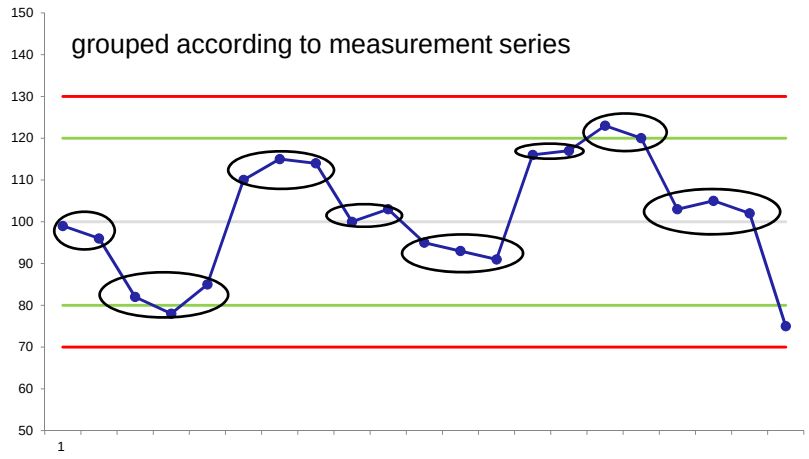
Defining a series of analyses

- **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

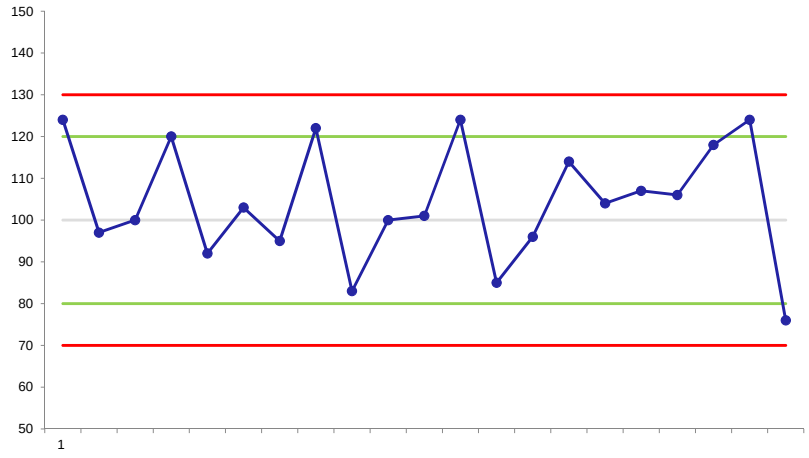
Series within series - Example



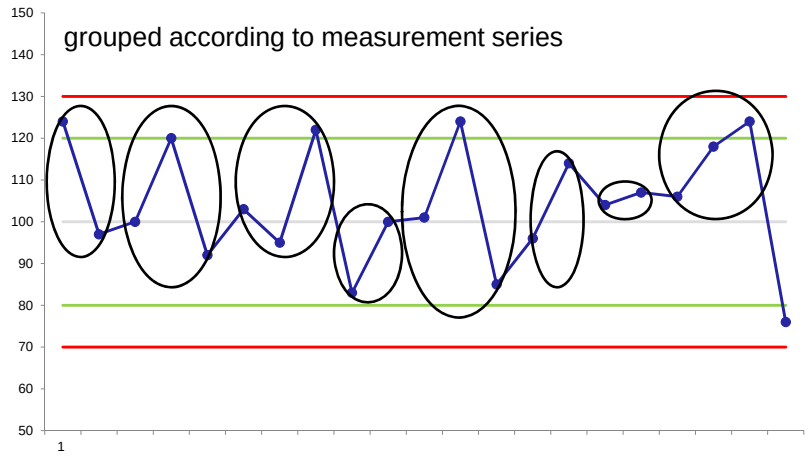
Series within series - Example



Series within series – Example 2



Series within series – Example 2



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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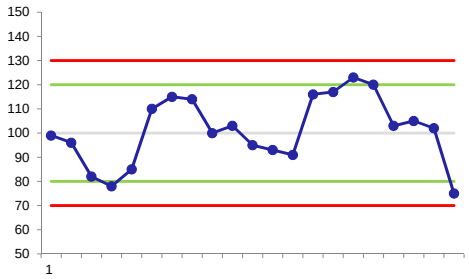
Input to database

- 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

Database input - example

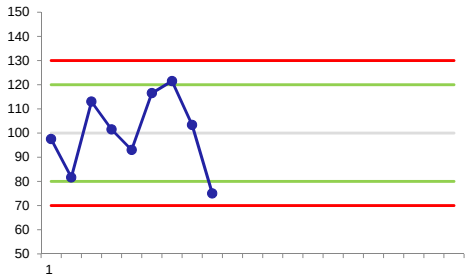
- Each response value for a control sample → a point in the X-chart, also when there is more than one measurement in a series:



S_{Rw} = 13.9

Database input – example 2

- Each point in the X-chart is the average of all response values for the control sample in the analytical series:



S_{Rw} = 15.6

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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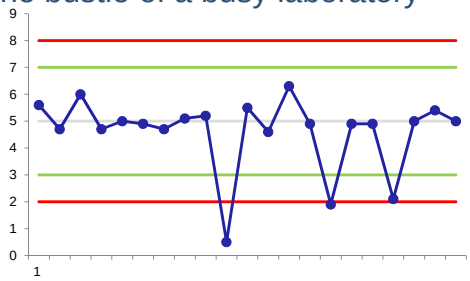
Analyses stopped unless action is taken

- 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



Analyses stopped unless action is taken

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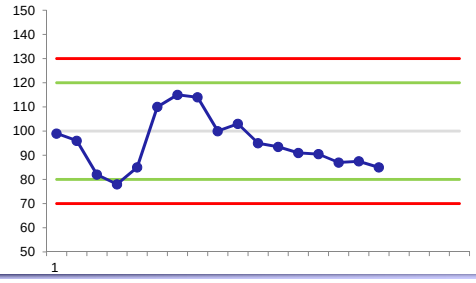
  - usually an initiative is taken when this occurs
  - in automated, (semi-)continuous systems there is a risk that an out-of-control situation is overlooked or neglected in the bustle of a busy laboratory
  - therefore LIMS systems should prevent data since last in-control from being reported unless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

Periodic review

- Principles as for every laboratory, look for
  - Trends



Periodic review

- Principles as for every laboratory, look for
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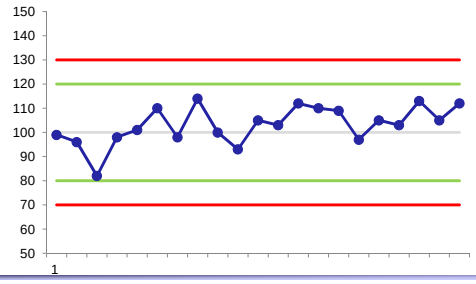
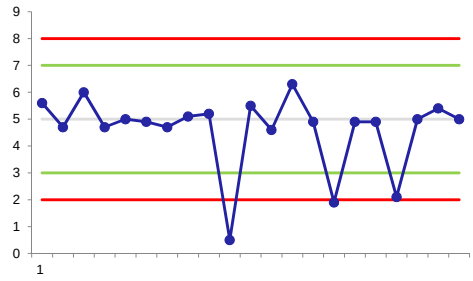
  - Shifts



Periodic review

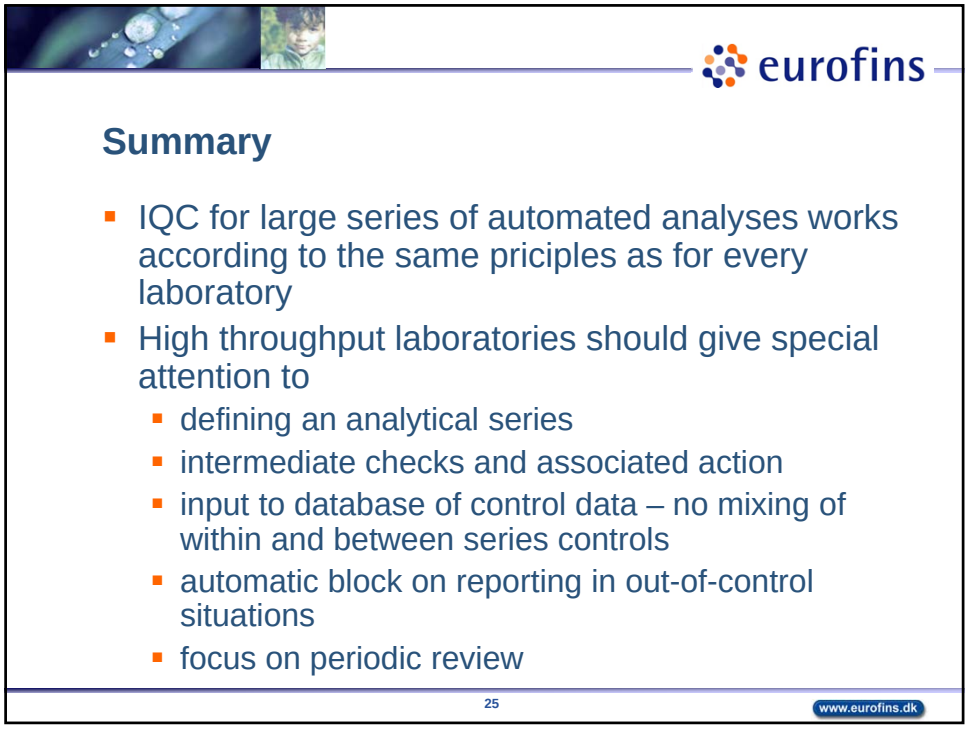
- Principles as for every laboratory, look for
  - Trends
  - Shifts
  - Frequency of out-of-control situations



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 priciples 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
25
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