Validation of a once a week installation of an automated compounding device for parenteral nutrition solutions

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Background

Production of individualised parenteral nutrition (PN) decreased after implementing standard PN. To keep few daily PN productions cost-effective, we decided to validate a once a week installation of the automated compounding device.

Material

Baxa MM12 in laminar airflow hood
GMP class A in cleanroom B
Water for injection
Nutrients: solutions for PN
Media-fill: trypscase soy broth

Specifications

Weighting pumped volume
Dosage, particles, media-fill

Accuracy: mean of expected value
Precision: Variation Coefficient (VC)
both: < 5%

Internal limits: +15% Na, +10% glucose, -15%/+10% K
Particles: according to Ph. Eur.
Media-fill: no contamination after incubation: 1 week at room temperature and 1 week at 32.5°C

Methods

Daily Operational Qualification (DOQ) (3 days)
Water for injection at each position
Weighing 10 times 0.5 to 40mL

Daily Performance Qualification (DPQ) (3 days)
Nutrients (but vitamins) at each position
Weighing 10 times 0.5 to 100mL
Production of defined PN control bags
Dosage of nutrients: Na, K, glucose

Weekly Performance Qualification (WPQ) (3 weeks)
Nutrients (but vitamins) at each position
Production of PN control bags
Dosage nutrients: Na, K, glucose and particles count

Weekly microbiology Qualification (3 weeks)
Bottle of trypscase soy broth at each position
Production of trypscase soy bags

Results

Daily operational and performance qualifications

<table>
<thead>
<tr>
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<th>0.5 mL</th>
<th>40 mL</th>
<th>100 mL</th>
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<tbody>
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<td>Accur.</td>
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<td>Prec.</td>
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<tr>
<td>Water</td>
<td>100.9%</td>
<td>3.2%</td>
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<tr>
<td>Nutrients*</td>
<td>99.3-10</td>
<td>2.7-3.9</td>
<td>100-100</td>
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* Volume pumped depending on nutrient

Particles:
Number of particles remained within Ph. Eur. limits

Media-fill:
No microbiological contamination was visible

Dosages of control PN, mean ± SD (DPQ & WPQ)

Conclusion

Validation proved adequate accuracy, precision and aseptic conditions along the week. The asepsis can only be guaranteed by a strict application of GMPS in a high quality compounding environment. In those conditions, PN can be produced safely all over a week with the same set installed. A week installation saves technician time (300 hours/year) and money (15 000 Euro/year).