



Leids Universitair
Medisch Centrum

WORKSHOP or INTERACTIVE DISCUSSION on Good Reconstitution Practices

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Nothing to disclose

Please appoint a chair in your group and a secretary who will present the results as a brief plenary .

- Start by reading the Resolution CM/Res(2016)2 on good reconstitution practices in health care establishments for medicinal products for parenteral use. (10 min)
- Start a discussion on the following subjects:

Group A.

Describe the highlights of a procedure to implement good reconstitution practices for a general hospital of a certain European country. Consider:

- the goals to be achieved,
- the manpower required and
- the expected timeframe.

Group B

Describe the highlights of a procedure to implement good reconstitution practices for a general hospital of a certain European country:

- Define prerequisites for the implementation of good reconstitution practices.
- Define minimum requirements for reconstitution in clinical areas of the chosen hospital

Group C

Describe the role of a designated person for good reconstitution practices. Consider:

- a job description and
- an advertisement

All groups

Try out the risk assessment checklist for:

- The preparation of a Potassium Chloride infusion pump of 50 ml, in order to administer 50 mmol/24 hr. The infusion is based on a licensed concentrated product in an ampoule of Potassium Chloride 2 mmol/ml, 10 ml.
- The preparation of a Metoclopramide injection of 10 mg. The injection is based on an ampoule of 5 mg/ml, 2 ml



Question 1

The European Directorate for the Quality of Medicines (EDQM) is a directorate of the Council of Europe.

Yes



Question 2

The resolution on good reconstitution practices (Resolution CM/Res(2016)2 was prepared to improve safety of reconstitution in clinical areas

Yes



Question 3

Reconstitution is the process to dissolve freeze dried medicines.

No, it is defined as manipulation to enable the use of medicines in line with SmPC or package leaflet



Question 4

The GRP resolution recommends that the designated person should preferably be a pharmacist.

Yes and this a great opportunity for hospital pharmacists!

- Risk assessment: ranking of reconstitution activities and the basis of the decision where reconstitution should take place
- Minimum requirements if reconstitution takes place in clinical areas
- Resolution implementation: crucial for increasing safety for patients receiving high risk medication

Please answer the Questionnaire about Resolution CM/Res(2016)2

THANKS!!!