Training and Qualification of Manufacturing Operators in French and Swiss Hospitals: A Survey

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**Objective:** To survey existing training programs and suggest modifications aimed at improving the qualification of operators in pharmaceutical manufacturing.

**Context:**

Statutory Regulations, ISO 9001

Pharmaceutical Manufacturing

Single patient preparations

Certification by the National Health Authority

Preparations of small sets
Methods

- An anonymous electronic survey of manufacturing practices in French and Swiss hospitals
- Based on the software «Sphynx»
- Featuring 21 queries grouped into four sections:
  - Type of institution
  - Type of initial and continuous training (both theoretical and practical)
  - Fields of qualification
  - Follow-up of qualification
- Survey sent directly to the Pharmacy Dept Head
- Survey open for one month
1) **Type of institution**

- 185 (34.5%) hospitals answered the questionnaire.
- 83 of them had facilities for pharmaceutical manufacturing.
2) Types of production

- Cytotoxic compounding
- Non-aseptic compounding
- Non-cytotoxic and non-TPN compounding
- Non-cytotoxic and non-TPN series
- TPN compounding
- Cytotoxic series
- TPN series
3) The current state of initial versus continuous training

Initial training
- No training: 12%
- Training according to the operator: 2%
- Systematically with training: 86%

Continuous training
- No Training: 6%
- Training with outside organization: 40%
- Internal training: 54%
4) Qualification, evaluation and follow-up

- Information on quality documents:
  - Operators in 21% of hospitals have only partial knowledge of quality documents.

- Assessment of the understanding of documents:
  - Operators in 34% of hospitals were asked to assess their understanding of such documents.
  - 20% of these hospitals asked for a written assessment, 80% for an oral one.
Discussion and Conclusion

- This survey brought to light remarkable disparities between hospitals in training and qualification procedures.
  - This can be explained by incomplete legislations regarding the training of operators.
  - In other words, many hospitals train their pharmaceutical staff according to in-house rules.