

Table of contents

Foreword

Introduction

1 How to easily create SOPs

- 1.1 Regulatory SOP requirements*
- 1.2 Overview of SOPs*
- 1.3 Template SOP*
- 1.4 Flowcharts for the actual procedure*
- 1.5 Questions for completing the text*

2 How to quickly create SOPs

- 2.1 Team approach*
- 2.2 Plenary discussion*
- 2.3 Expected duration*
- 2.4 Backward timeline setting (max. 6 weeks)*
- 2.5 Actions*

3 Terrific team building

- 3.1 Lifting your organization*
- 3.2 Involvement of the team and staff functions*
- 3.3 Create and review*
- 3.4 Feedback & training*
- 3.5 Finalization and usage*
- 3.6 Repeatable*

4 SOP strategies

- 4.1 High level, low level SOPs*
- 4.2 Actual procedure text and flowcharts*
- 4.3 Quality control steps*
- 4.4 Responsibilities*

5 The six weeks SOP program

- 5.1 Plenary start*
 - 5.1.1 Which SOPs need (re-)creation?*
 - 5.1.2 The idea how to (re-)create these SOPs?*
 - 5.1.3 SOP template*
 - 5.1.4 Strategies to choose from*
 - 5.1.5 Setting backward timelines*
 - 5.1.6 Taking actions, taking responsibilities*
 - 5.1.7 Expectations*
- 5.2 Step-by-step creation & review*
- 5.3 Weekly follow-up*
- 5.4 Feedback & training*
- 5.5 Finalization and usage*

6 Evaluation

- 6.1 Evaluating disappointments and success during the program
- 6.2 Actions to improve the program and evaluating overall success.

7 Motivation

- 7.1 To start
- 7.2 To keep going
- 7.3 To finish

8 How to keep up the good spirit

- 8.1 Ideas for a 'party'
- 8.2 Tips for a reminder
- 8.3 Ideas to celebrate a milestone
- 8.4 Tips for the next challenge

9 Concluding the program

- 9.1 What you've experienced
- 9.2 What you've learned
- 9.3 Repeatable
- 9.4 Thank you

10 Additional support

- 10.1 Coaching
- 10.2 Ready-to-use material

11 Bonus: clinical data management SOPs including computerized system validation