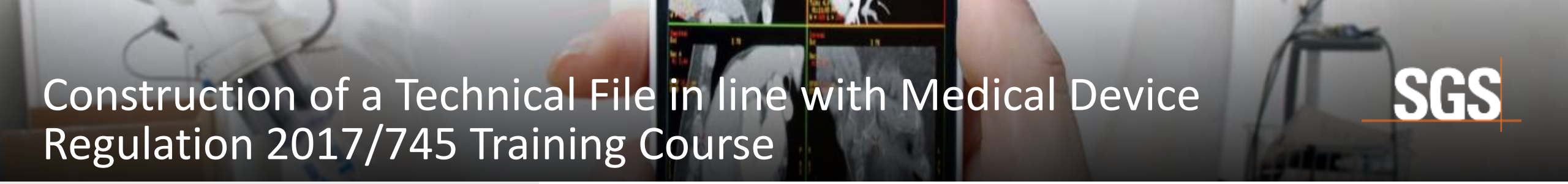

# Construction of a Technical File in line with Medical Device Regulation 2017/745 Training Course

## COURSE DESCRIPTION

This course aims to provide accurate and current information to allow medical device manufacturers to meet the global regulatory, quality and technical requirements for medical devices. This allows manufacturers to place products on the market with confidence and in the minimum time.

| | | | |
|---|---|---|---|
| DURATION: | 1 Day<br>8 Hours | DELIVERY: | Face to Face<br>VILT |
| ACCREDITATION: | SGS | LANGUAGE: | English |

> Medical Device Regulation 2017/745.

## LEARNING OBJECTIVES

Upon completion of this course, you will be able to:

- Understand the technical documentation requirements of Medical Device Regulation 2017/745 and how to interpret them
- Prepare technical documentation to meet the requirements of the Medical Device Regulation 2017/745
- Use the references and guidance documents available to further enhance their understanding of the documentation requirements

## AUDIENCE

This course is designed for:

- Quality and regulatory professionals
- Engineers
- Supervisors and Management

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## COURSE CONTENT

- Know and understand the requirements of the Medical Device Regulation 2017/745 for technical documentation.
- General requirements inc. description, intended use,
- medicinal substances, animal tissue, classification, links to other directives, declaration of conformity
- Manufacturing specifications
- General safety &performance requirements
- PMS/PMCF

## PRIOR KNOWLEDGE

You are expected to have a working knowledge of the ISO 13485 standard, and the Medical Device Directive 93/42/EEC. Inc. 2007/47 amendment.

## COURSE CERTIFICATION

On completion of this course you will receive a Certificate of Attendance.


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