

2-day In-person Seminar:

Medical Devices - ISO 13485 -Do you really know what you need to?



Jason Teliszczak

CEO/Founder, JT Environmental Consulting

Mr. Jason Teliszczak is an entrepreneur with a passion for ensuring quality through proper processes and strengthening any organization to better their outputs. After earning a B.S. in Environmental academia and to ensure his vision would not be put to waste, he built his own successful consulting firm, JT Environmental Consulting, and has quickly become an expert within the Quality, Safety, Security and Environmental industries. With more than a decade of consulting experience, Mr. Teliszczak assists his clients in setting targets and achieving goals.

Overview :

A detailed look at each section of the standard.

Real world examples of what to expect, and what to prepare and repeal within the audit guidelines.

What must a documentation system look and feel like to ensure compliance?

These and many other key details to ensure that your organization has the ability and knowledge to ensure that ISO 13485 is within your grasp.

Clean rooms 101, we can assist in what to do and what not to do. From the infrastructure, to the maintenance, PPE, etc. It is a holistic system that must be maintained at optimal standards at all times.



Price

Price: **\$1,495.00** (Seminar for One Delegate)

Register for 5 attendees

Price: **\$4,485.00** You Save: \$2,990.0 (40%)*

ENROLL

**Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.





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Agenda:

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Lecture 1:

•Foundation of this standard (Clauses 0-3)

•Scope & normative references

Lecture 2:

- •Scope & normative references cont.
- Definitions
- •Quality Manual System (Clause 4)

Lecture 3:

Quality Manual System cont.Management Responsibility (Clause 5)

Lecture 4:

•Management Responsibility cont.

•Resource Management (Clause 6)

Day Two

Lecture 1:

- Recap
 - •Resource Management cont.

Lecture 2:

•Product realization (Clause 7)

•Measurement, Analysis - (Clause 8)

Lecture 3:

- •Measurement, Analysis... cont.
- •Annex A & B
- Recap

Lecture 4:

- Implementation
- Internal Audits
- Interviews
- Documentation

Areas Covered in the Session:

- An overview of the standard and the different areas needed to create, maintain, and sustain a proper documentation system to ensure certification.
- Know what to look for and where to prepare to enable one's organization and personnel to assist in an audit for certification.
- Clean rooms
- Supplier demands
- Quality from when materials are received, until after the devices leaves the facility.
- Annual upkeep
- Management representation and participation.

Who Will Benefit:

- Quality Managers
- EH&S Reps
- Quality Control
- QCQA
- CEOs
- Sales
- Buyers
- Vendors



	Group Participation
10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

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Look forward to meeting you at the seminar

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