MEDICAL TECHNOLOGY –

HOW TO AVOID COMMON TESTING AND CERTFICATION PITFALLS

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AGENDA

1. Avoiding typical EMC pitfalls
2. Avoiding typical SAFETY pitfalls
3. Avoiding typical RADIO pitfalls
4. Avoiding typical CERTIFICATION pitfalls

THE ODDS OF SUCCESS

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IDENTIFY
THE REQUIREMENTS

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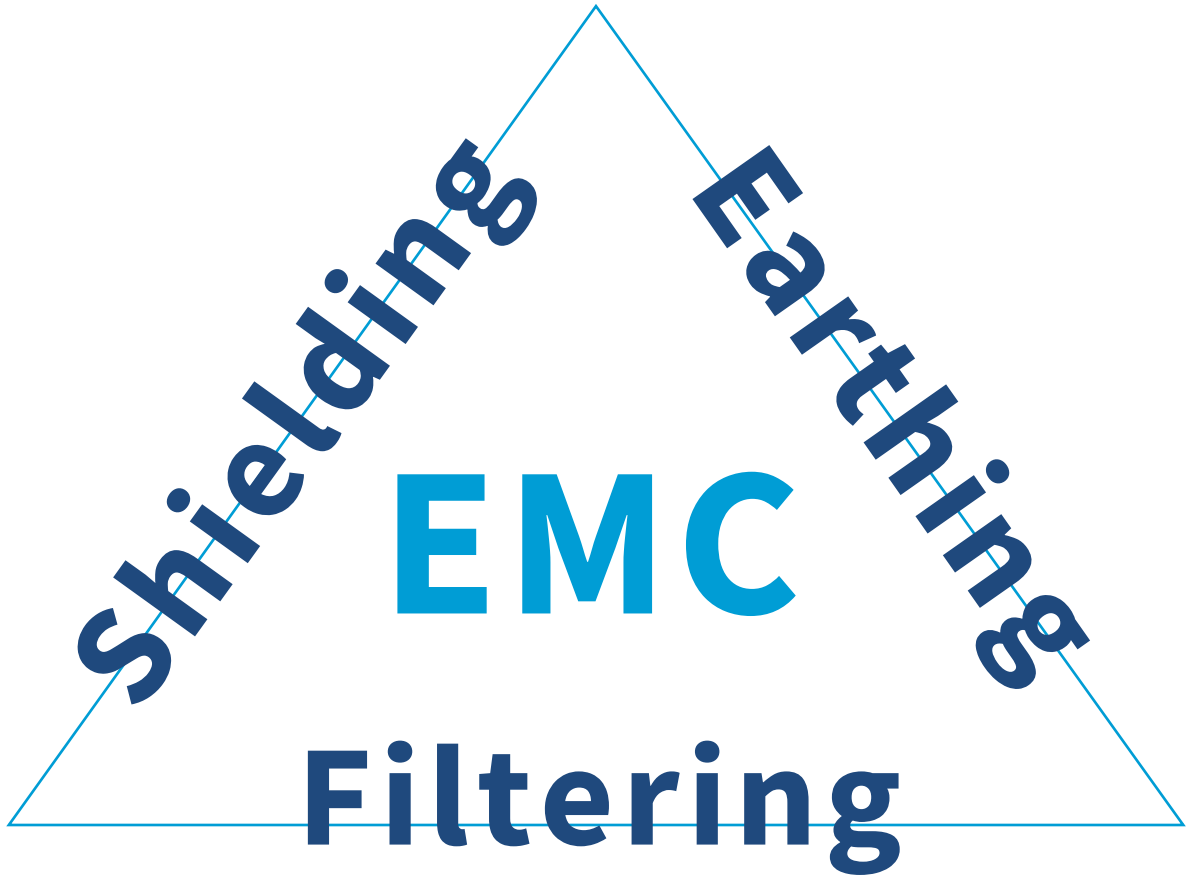
- Country or Region Legal Requirements
- Market Expectations
- Specific Customer Requirements

AVOIDING TYPICAL EMC PITFALLS

The 3 principles of good EMC design:



- Use COMPLIANT COMPONENTS - and as intended
- CE + CE ≠ CE

EMC TEST PLAN

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Identification of the product and its intended uses: Tests required. Limits and levels. Spot frequencies.

Consolidation of the different requirements of standards. Justification for any deviations. Multiple voltages and frequencies. Global bodies have different views.

Country	Voltage	Frequency
Argentina, Australia, Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, India, Ireland, Israel, Italy, Malaysia, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Russia, Serbia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Ukraine, United Kingdom	230 Vac	50 Hz
Belarus, China, Indonesia, Thailand, Turkey	220 Vac	50 Hz
Canada, United States	120 Vac	60 Hz
Japan	100 Vac	50 Hz or 60 Hz
Kenya	240 vac	50 Hz
Mexico	127 Vac	60 Hz
South Korea	220 Vac	60 Hz

Voltage	Frequency
230 Vac	50 Hz
120 Vac	60 Hz
100 Vac	50 Hz
220 Vac	60 Hz

EMC TEST PLAN

Identification of the product and its intended uses: Tests required. Limits and levels. Spot frequencies.

Consolidation of the different requirements of standards. Justification for any deviations. Multiple voltages and frequencies (Global bodies have different views).

Configurations. Modes of operation. Intended environments. Ports and cable lengths. Power supply characteristics. Accessories.

Basic Safety and Essential Performance. Primary functions. Pass/fail criteria. Methods of monitoring

AVOIDING TYPICAL SAFETY PITFALLS

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- Timely availability of documentation

Required Documentation

- Application forms
- Circuit diagrams
- Engineering drawings & block system diagrams
- Rating label drawing and details of warnings/markings to be on the product
- Component list
- Details about alternative components
- Manufacturers' data and Approval Certificates on polymeric materials used for enclosures and PCBs
- Datasheets and Approval Certificates for critical components
- Installation and User Instructions
- Where applicable, supporting reports for aspects of testing which are not covered in the quoted test program (e.g., software/ laser/ ingress protection)

AVOIDING TYPICAL SAFETY PITFALLS

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- Timely availability of documentation

- Missing or incorrect documentation
  - Application forms
  - Component diagrams/drawings
  - Instructions
  - Markings, warnings and symbols
  - Approvals for critical components

Critical Components not being IEC certified – and/or evidence of adequate certification not being supplied/available

AVOIDING TYPICAL SAFETY PITFALLS

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- Timely availability of documentation
- Missing or incorrect documentation
- Sample availability
  - Final samples supplied in good time
  - Supplied in working state, with support equipment
  - Spare samples or safety critical components

AVOIDING TYPICAL RADIO PITFALLS

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- Conformity of radio module/device to be checked
- FCC grant approval may not be adequate
  (e.g. mobile/stationary, not for co-location)
- Co-location of radio devices can cause intermodulation
- Additional modes require testing for EMC
- **Configured for test modes**

TESTING – PRE-COMPLIANCE

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EMC / Radio

Pre-compliance testing – i.e. ‘quick’ scans

Support with finding solutions to EMC issues

Safety

Prototype design review

AVOIDING TYPICAL CERTIFICATION PITFALLS

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- Awareness of regulations. Upcoming changes in the UK and EU
- Age of previous testing - tested to CURRENT standards?
- Certification and regulatory approval can take longer than you think
- Think about the critical path

AVOIDING TYPICAL CERTIFICATION PITFALLS

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- Don’t overlook Software (& Useability) – and allow sufficient time
- Application must match the product
- Component obsolescence – supply data for alternative components

Planning and Timing

ENGAGE EARLY

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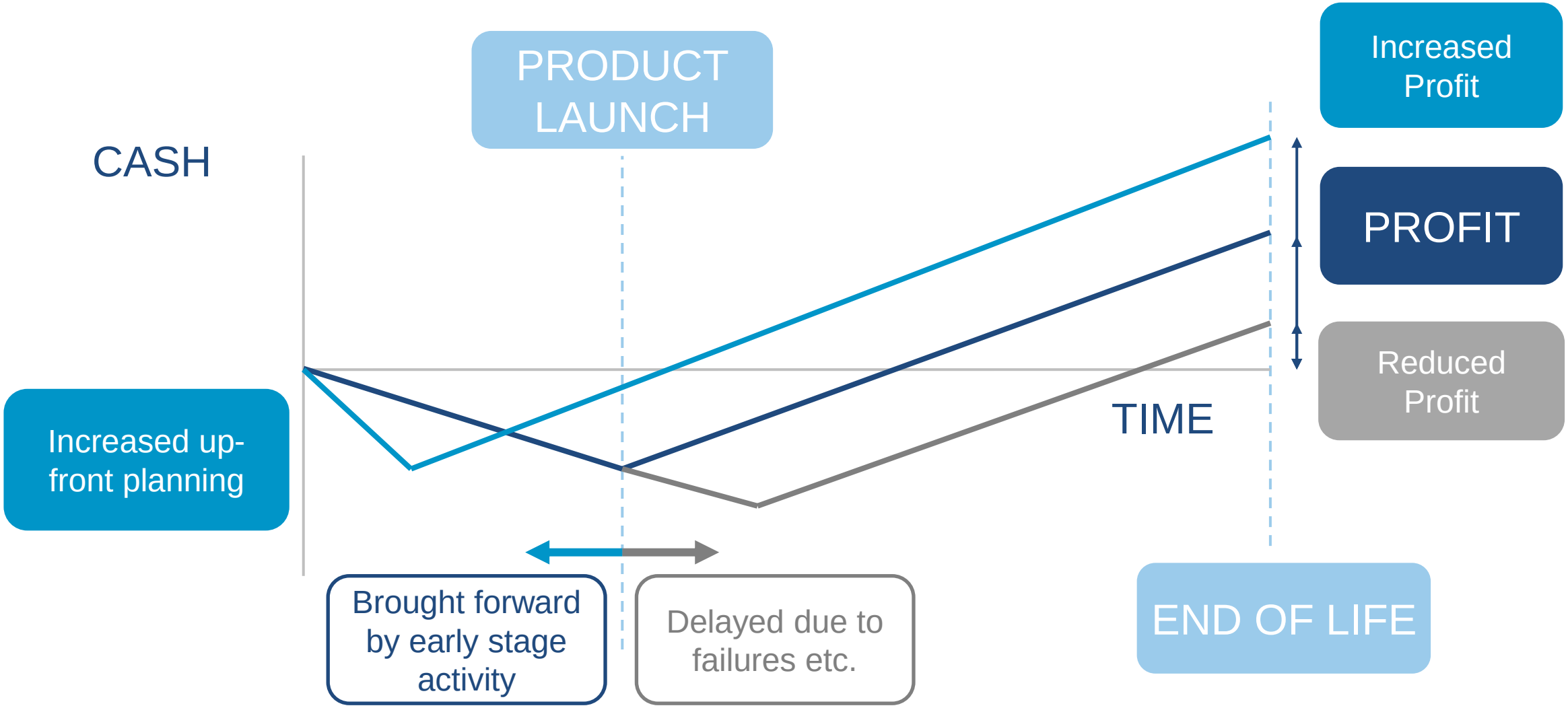

BE PREPARED

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COMPLIANCE STRATEGY

THANK YOU

Q&A

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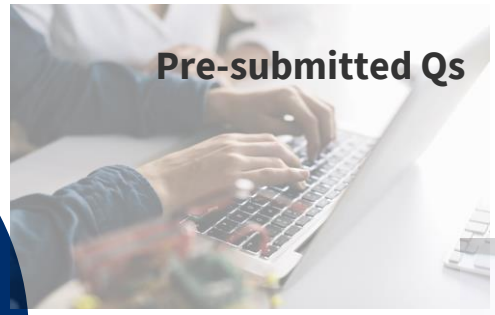

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