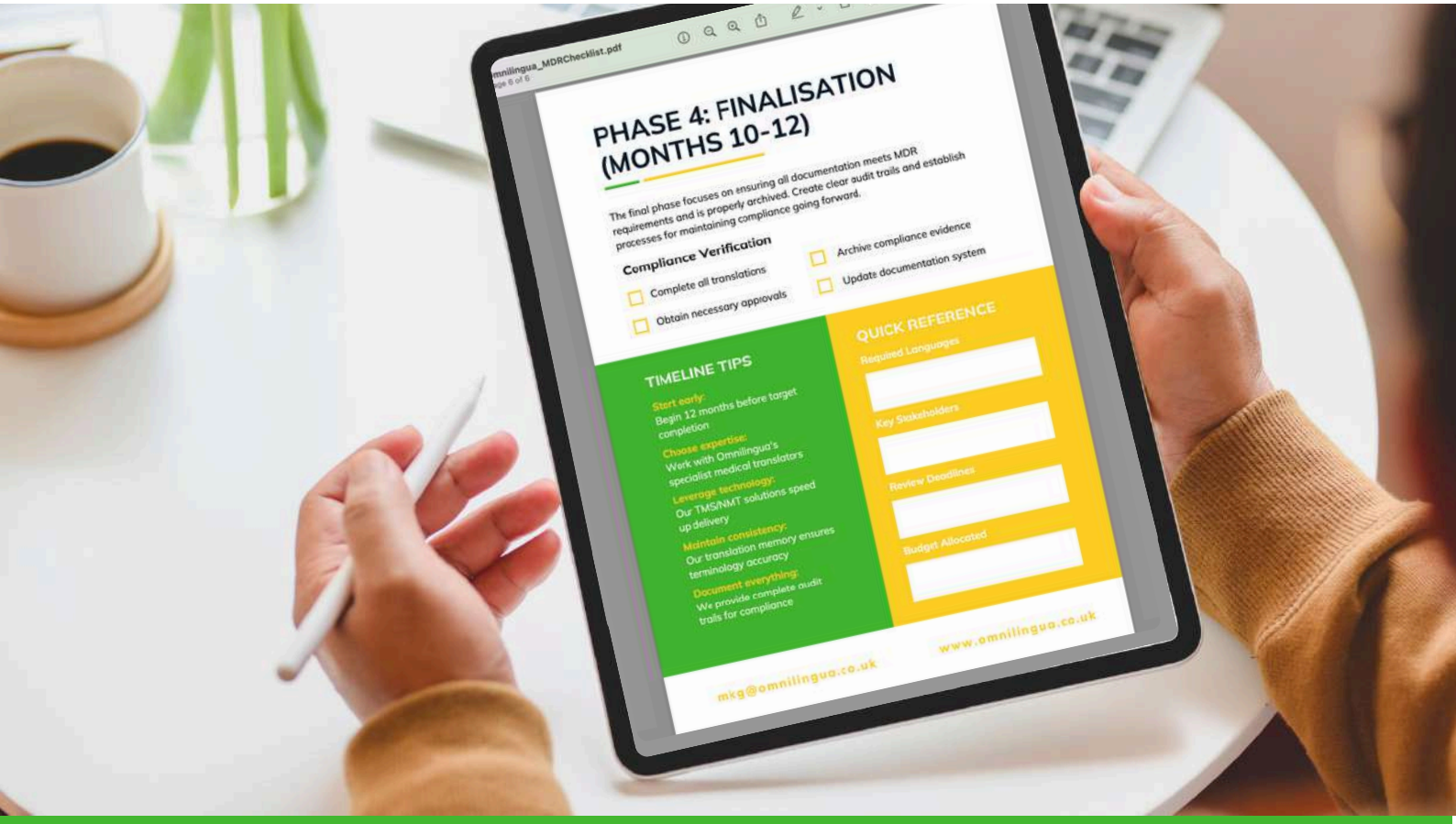
MDR TRANSLATION CHECKLIST



MDR Translation Compliance: Your 12-Month Planning Timeline

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WHO WE ARE

For over 25 years, Omnilingua has delivered specialist translations for highly regulated industries, from healthcare and pharmaceuticals to engineering and IT. Our translators are subject matter experts working exclusively in their native language and specialised fields, ensuring exceptional accuracy in medical and technical translations.

We combine innovative Translation Memory Software with Neural Machine Translation to deliver faster, more cost-effective solutions. Our comprehensive service includes multilingual desktop publishing and project management, while ensuring compliance with regulations like CE markings and MDR for healthcare products.

Use this checklist to plan every step of your MDR translation compliance journey and ensure you achieve accurate, compliant translation for your medical devices.

TRANSLATING COMPLEXITY WITH EXPERT PRECISION FOR OVER 25 YEARS

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PHASE 1: ASSESSMENT (MONTHS 1-3)

During this initial phase, focus on gathering data and understanding the scope of work. A thorough assessment now will prevent costly surprises later. Consider both immediate needs and long-term maintenance requirements.

Documentation Audit

- [ ] Create inventory of existing translations
- [ ] Identify gaps in current documentation
- [ ] Review target market requirements
- [ ] Assess internal translation resources

Documentation Audit

- [ ] Calculate translation volume (we provide quick, accurate cost estimates)
- [ ] Evaluate technology needs (our TMS/NMT solutions reduce costs)
- [ ] Estimate review process costs (native-speaking subject matter experts)
- [ ] Plan for ongoing maintenance (translation memory reduces future cost

PHASE 2: PREPARATION (MONTHS 4-6)

This phase establishes your foundation for success. Create clear processes and guidelines that will ensure consistency across all translations. Strong preparation reduces risks and streamlines future work

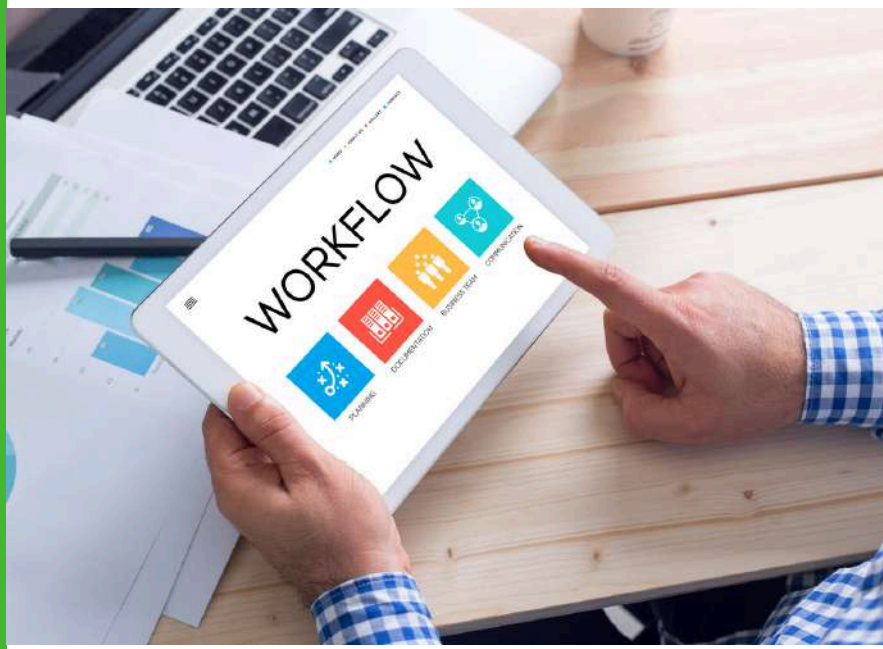
Documentation Set Up

- [ ] Create translation glossary
- [ ] Define style guidelines
- [ ] Establish version control system
- [ ] Set up review workflows

Team Organisation

- [ ] Assign project ownership
- [ ] Identify review team members
- [ ] Partner with Omnilingua's medical translation experts
- [ ] Establish clear communication channels with our project team

STRONG PREPARATION REDUCES RISKS AND STREAMLINES FUTURE WORK



PHASE 3: IMPLEMENTATION (MONTHS 7-9)

Begin the actual translation work with your highest-priority documents. Monitor processes carefully and adjust workflows as needed. Regular quality checks during this phase help prevent issues from scaling across multiple languages.

Translation Process

- [ ] Begin high-priority translations
- [ ] Implement quality checks
- [ ] Test review workflows
- [ ] Document validation procedures

Quality Control

- [ ] Conduct terminology reviews
- [ ] Verify formatting consistency
- [ ] Check regulatory compliance
- [ ] Validate technical accuracy

PHASE 4: FINALISATION (MONTHS 10-12)

The final phase focuses on ensuring all documentation meets MDR requirements and is properly archived. Create clear audit trails and establish processes for maintaining compliance going forward.

Compliance Verification

- [ ] Complete all translations
- [ ] Archive compliance evidence
- [ ] Obtain necessary approvals
- [ ] Update documentation system

TIMELINE TIPS

Start early:
Begin 12 months before target completion

Choose expertise:
Work with Omnilingua's specialist medical translators

Leverage technology:
Our TMS/NMT solutions speed up delivery whilst reducing costs

Maintain consistency:
Our translation memory ensures terminology accuracy

Document everything:
We provide complete audit trails for compliance

QUICK REFERENCE

Required Languages

Key Stakeholders

Review Deadlines

Budget Allocated