# Quality Manual

Omnilingua Limited

BS EN 15038





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## I. Introduction

After analysis of our processes Omnilingua hereby declares its conformity to the internationally recognised industry service standard **BS EN 15038:2006** for translation services. This document details our procedures and records kept in compliance with this standard.

Founded in 1998, Omnilingua specialises in Medical Translation. As a consequence Omnilingua has invested considerable resources in building-up one of the most comprehensive networks of professionally qualified and experienced medical translators in the industry. In addition, our Project Managers have been chosen carefully being responsible for smooth co-ordination of all assignments and clear communication between all participants. We have also invested in the latest technology to make sure that we can provide best service to our clients in the most efficient manner.

With this Quality Manual we will give you an insight into our company and service to make it easier for you to understand all the processes that constitute every project. We illustrate our Quality Management System, how we measure the quality of our work and associated documented procedures. We describe how our company is organised and who is responsible for each department. Client satisfaction is paramount and as a result we will show you in detail how our clients evaluate our work. We also give you an insight into the relationship between ourselves and our clients. After this we explain our project management systems, which is one of the most important aspects. We will explain how we manage all translation projects and who is responsible at each stage. Of course our translators are the most important component of the translation process. Because of this we will explain in detail how we choose our translators for every project and how we make sure that we only use appropriate specialists in the subject for translation. In this section we will also give a lot of information about the review process after initial translation. Then we will briefly explain our use of language and publishing technologies to improve efficiency and fully satisfy client requirements. Finally, we have a section on our internal staff and our commitment to their continuing professional development to enhance their qualifications.

We are committed to a policy of continuous improvement and welcome feedback from all parties to assist us in this in addition carrying out our own regular internal process reviews.

## II. Scope

This manual sets out to demonstrate Omnilingua's quality control procedures in line with the standard "BS EN 15038 Translations services – service requirements". The BS EN 15038 standard is the UK implementation of the BS 15038 standard of the European Committee of Standardization

## **III. Definitions**

To make sure that every reader is able to understand our Quality Manual, and to make sure that there are no misconceptions about certain words in it, Omnilingua has prepared a list of ambiguous or specialist words.

	1
'Added value service'	means the services, which can be provided by Omnilingua in addition to translation.
'CAT'	means Computer Assisted Translation Tools.
'Client'	means any person, firm or company to whom the Company shall supply or contract to supply work.
'The Company'	means OMNILINGUA LIMITED.
'Competence'	means the demonstrated ability to apply knowledge and skill.
'Interpreting'	means the rendering of spoken information in the source language into the target language in spoken form.
'Locale'	means the linguistic, cultural, technical and geographical conventions of the target audience.
'Proofreading'	means checking of proofs before publication.
'Review'	means to examine a target text for its suitability for the agreed purpose and respect for the conventions of the domain to which it belongs and recommend corrective measures.
'Reviewer'	means the person who reviews.

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'Revise'	means to examine a translation for its suitability for the agreed purpose, compare the source and target texts, and recommend corrective measures.
'Reviser'	means the person who revises.
'Source text'	means the original text - the text, which is being translated.
'Target text'	means the translated text.
'Translation'	means the rendering of written text in the source language into the target language.
'Translation Service Provider (TSP)'	means the organization or person who supplies translation services.
'Translator'	means the person who translates.
'Work'	means translation, interpreting, typesetting or any other services supplied by the Company.

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# 1. Quality Management System

## 1.1. Omnilingua Quality Management System

Our Quality Management System ensures that all clients receive the highest standard of service. It is structured as follows:

#### **PLAN**

To obtain the best results we have to analyse each requirement to establish the best resources to use, both human and mechanical, to provide the highest standard of translation services.

#### DO

Here we start the process of translation, implement contract and project management systems in order to realise the translation process.

#### CHECK & ACT:

Here we analyse and then correct possible failings and non-conformities in the translation process and try to plan and implement ways of preventing this happening again. This step also includes tasks such as getting feedback on the translation services which have been delivered (e.g. use of customer questionnaires).

## 1. PLAN

#### Planning

- Identify and demarcate services conforming to the standard
- Identify use of sub-contractors
- Identify and appoint or prepare to subcontract competent translators
- Identify and ensure availability of adequate technical resources
- Identify and state quality management system objectives

#### 2. DO

- Contract management
- Project management system
- Translation process

Omnilingua Quality Management System

#### 3. CHECK

Assessing performance

- Monitoring and measurement
- Evaluation of compliance
- Analyse and handle nonconformities

#### **4. ACT**

Making improvements

- Corrective Action
- Continuing professional development

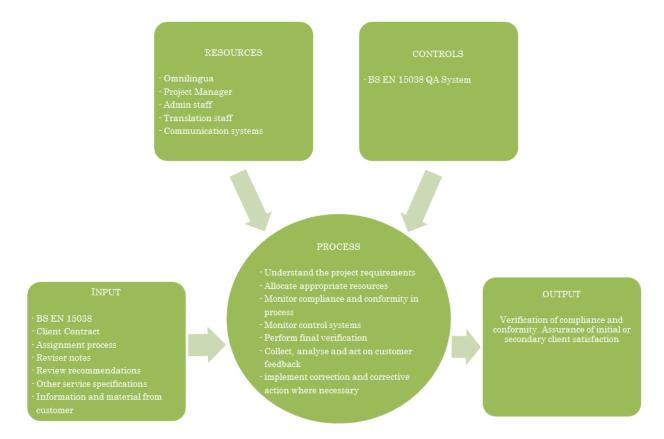
## 1.2 Quality Control of the translations

To obtain optimal translation results there must exist expertise and cooperation between all parties. The translators must have the required qualifications and expertise in medical and/or technical translations. During the selection process when we are deciding which translator is the most suitable, we make sure that they all have the above-mentioned requirements (details see Section 4).

In addition our Company carries out such tasks as proof reading, editing and desktop publishing. All parties use special language and publishing technology (see Section 5) to provide professional translations.

A final stage of the translation process involves liaison between client overseas product specialists and Omnilingua. Based on their in-depth knowledge of the products and target markets they can advise on specific stylistic and terminology requirements as well as review final Omnilingua versions before final publication.

Below you can find a graphic which illustrates the quality control process.



# 2. Relationship between Client and Company

## 2.1 Enquiry and Feasibility

We ensure that we handle all enquiries as soon as possible. As well as ensuring we satisfy the wishes of our clients we also ensure that our service is applicable to all requirements of the BS EN 15038 standard. At all times we try to make quotations to clients as precise as possible.

### 2.2. Quotation or proposal

This procedure is formally documented in the form of a *Project Proposal Form* and takes into consideration the language pair, the subject and the target audience. It also looks at the formatting, the required software, the volume, deadline and previous translations and other reference material. As well as the informing on pricing it also forms the basis of the agreement between Client and the Company.

#### 2.3. Contract

The contract is a very important component for our work and is formally documented in the form of a *Service Contract Form*. It is the agreement between the client and The Company about the work that should be done. Here it is very important for the client to provide clear specifications otherwise there could be misunderstandings. The contract is the basis of the project. Nobody who is involved in this contract is allowed to act against the regulations of the contract. Every participant needs to fulfill his or her responsibilities. The formulation of the contract transforms the parties' promises into obligations. Any deviations from the original contract terms require either a new contract issued or a separate written addendum. However, because we are BS EN 15038 standard compliant, many of the requirements of the standard are included as terms of the contract. This saves the formal inclusion of these elements as separate terms of the contract. Additionally, when contracting work in the rest of Europe, there is more concordance than would normally be the case.

## 2.4. Terms and Service Specifications of a Contract

The Terms and Service Specifications are written in our *General Terms of Business*. We declare that they conform to the BS EN 15038 standard. For every new client our general Terms of Business must be agreed and signed for by them.

## 2.5. Dealing with Project related Client Information

We ensure that our company deals carefully with all information from and about our clients. The Company shall at no time disclose to any Third Party any information acquired in the course of carrying out Work on behalf of the Client without his permission. The Company is happy to sign any client confidentiality agreements.

# 3. Project Management

In this section we will explain our Project Management to you. Project Management is a very important component of the whole translation process as a co-ordination exercise for all participants in our projects. We will explain our workflow to you to make it easier for you to understand how our company works. We will also give you some information about our Project Managers, who manage all of our projects and who are responsible for communication between client, Company and translators.

## 3.1. Project Managers

Every project has one dedicated Project Manager, who is responsible for the tasks that are included in each assignment. The project manager is tasked with supervising the preparation of the translation process to make sure that everything necessary to start the project is in conformity with all requirements. This includes customer based requirements, standard based requirements and our own management system based requirements. All requirements need to be evaluated so that suitable personnel can start working on the project. Every project is documented with a numbered *Project Record Sheet* created and updated as project progresses.

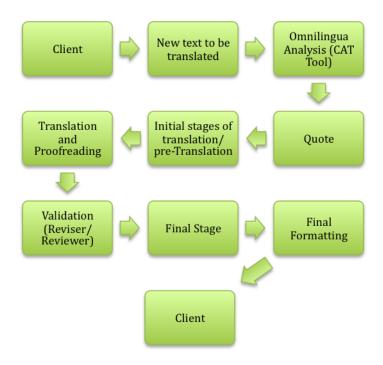
It is usual for the following tasks to be included in this preparation process with the Project Manager being mindful to the requirements of the Standard that apply to each one of these. The Project Manager has to assign translators to the project, revisers and, if applicable, reviewers. They have to issue clear instructions to all parties involved in the project and have to ensure that communication lines are clearly established for maintenance of contact with all parties involved in the project as, and when, appropriate. Speedy communication is especially important to solve problems that can occur during the translation process. Enabling and monitoring consistency in translation will also be part of the translation process.

Along side the Project Record Sheet the Project Manager also creates a staged timetable that requires a simple process of checking progress of the project against the timetable. It is in this type of process where there are a range of known hazards for successful achievement but equally well-known preventive and corrective measures can be built into the project plan by the Project Manager. There should also be a clear delivery schedule for the project and documented clearance for delivery. Day-to-day communication between the client and the Company is essential in this process.

We confirm that our Project Managers work on the basis of the BS EN 15038 Standard and do everything that is required by the Standard to conform to this. All our Project Managers are highly-qualified with considerable experience in the field of Project Management.

#### 3.2. Process of Work

In this process we describe how we deal with every project on behalf of our clients. The process of work is split into distinct steps. Broadly, these consist of preparation, the translation process itself and the final stages after initial translation.



#### 3.2.1. Preparation

The first step of the preparation is to check if the source text of the client complies with the initial agreement between the client and the Company. If necessary there might be the requirement to make a new agreement. If conformance is given the next step is project registration and project assignment. It is also part of this process to choose a Project Manager, who is responsible for the project and who needs to create a staged timetable, which is the guideline for every participant of the project. Furthermore the Project Manager is the sole contact person for the client. The next important step in the preparation concerns the technical aspects. Here we need to analyse the formatting, the software requirements, and the volume of the project. We can then assess how much time the project will need. Then there is the linguistic aspect. As well as the language combination it is also important to look at the subject-matter and the target audience or readership. In the preparation process we also check if we have met all requirements of the contract. Each project also gets a unique identification number to distinguish it from other projects as well as creation of a unique Project Record sheet.

In some cases the next step is creation of a basic glossary of key terms relating to the document for translation as well as any translation memory preparation. This is one of the tasks of our Project Assistants and/or Localisers, selected carefully for this task. We would then send a translation or a pre-translated file, a glossary optionally, instructions, a reference document to show final layout and a contract to the translator. We select our translators dependant on the language pair, their experience, specialisation and the deadline.

This preparation is very important because every project needs to be well regulated to make sure that every stage in the work cycle is traceable. The preparation stage also creates clear areas of responsibility for every participant and it should create a smooth workflow thereby ensuring we provide the very best service to our clients.

#### 3.2.2. Process of Translation and Validation

After successful preparation comes the main translation stage. The translator has to follow the assignment instructions given by the Project Manager. The translator needs to pay particular attention to such aspects as terminology, grammar, lexis, style, locale, formatting and intended audience during the process of translation. To assist them all our translators use the latest language technology (e.g Trados CAT tool) which is explained in more detail later. After initial translation comes the review stage. A reviser is appointed to check the work of the translator. In many cases they also have to check the layout and correct formatting of the translation. If agreed in the contract we also use a third party reviewer/proofreader to check the translation again. After this the translation is normally sent for validation to a local checker appointed by the client. In chapter 4 you will get a precise explanation about the translators, revisers, reviewers and proofreaders.

#### 3.2.3 Final stages

After successful validation by the local checker or Reviser referred to comes the final stage of the process. Final tasks include cross-checking the local checker changes with the initial translator, updating the translation memories and any term glossaries.

Checks are made against the following main items:

- meaning has been conveyed as well as correct style/tone for target audience
- no omissions or other errors
- defined specifications met

Any final formatting issues are then resolved and then the final product is cleared for delivery to the client.

## 3.3. Payment and Costs

Our standard payment terms are covered in our General Terms of Business. Non-standard payment terms and costs are described in our Proposal Form and Contract. Unless stated otherwise all costs are fixed not approximate.

## 4. Translators

In this section we provide more information about our translators. We explain how we choose our translators for a project and their key competences. Despite this, it is still necessary to have all of their work reviewed by third parties to check accuracy as 'best practice'.

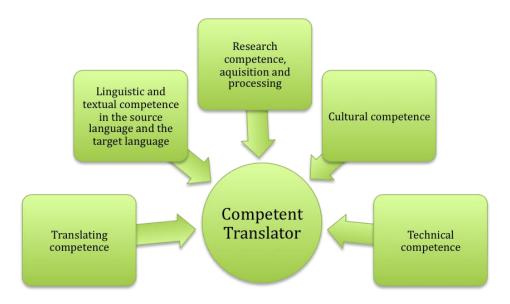
#### 4.1. Selection and Competences of the Translators

The selection of the translator is one of the most important aspects in the preparation of the translation. It is very important to choose translators with suitable qualifications and experience in the particular field of Medical translation. The Company has one of the most comprehensive lists of professionally qualified and experienced translators built up over years. As all our translators are well known to us we trust the work they produce. Most of our translators have a background in medicine and a minimum experience of 5 years in translation.

Each Approved Translator has a *Translator Record* kept electronically on a special database which, as well as contact information, keeps details of specific skills and competences, language pairs, IT/technology expertise, rates and other comments and information as well as a list of previous work completed for the Company via a project number recognition system. This is updated regularly by Project Assistants.

There are 5 competences that are required and stated by the BS EN 15038 standard and which are followed by the Company. The first competence that a translator should have is "Translating competence". All our translators have the ability to translate to the required level. They can assess the problems of text comprehension and text production and have the ability to render the target text in accordance with the client-TSP agreement. The second competence a translator should have is the "linguistic and textual competence in the source language and the target language". The linguistic and textual competence includes the ability to understand the source language and mastery of the target language. Textual competence requires knowledge of text type conventions for as wide a range of standard-language and specialized texts as possible, and includes the ability to apply this knowledge when producing texts. As well as being native speakers of the target language all our translators are fully familiar with the source language to understand all nuances. The third competence is "Research competence, information acquisition and processing". Research competence includes the ability to efficiently acquire the additional linguistic and specialised knowledge necessary to understand the source text and to produce

the target text. Research competence also requires experience in the use of research tools and the ability to develop suitable strategies for the efficient use of the information sources available. They need to be able to search for information that they need for the translation to provide a very good target text for the client. By being specialist Medical translators not only do the translators have an in-depth knowledge of the subject-matter, they also have a comprehensive library of reference material to assist them and strong research skills. They also readily revert back to the Client via the TSP with any subject-related queries and ask for all available product-related reference material to assist them. The fourth competence is "Cultural competence". Cultural competence includes the ability to make use of information on the locale, behavioural standards and value systems that characterise the source and target cultures. We, the translation service provider, make sure that all of our translators strike the right tone for the given audience or readership. By living in the target country all translators are fully aware of and current with the cultural background of the target language. The fifth competence that a translator should have is "Technical competence". Technical competence comprises the abilities and skills required for the professional preparation and production of translations. This also includes the ability to operate technical resources. We make sure that all our translators are able to deal with the technical requirements that are required by our clients and by us.



In addition, any new translators that are put on our approved list require these same 5 competences. They are thoroughly vetted and test translations undertaken to check suitability.

#### 4.2. Reviser

The reviser or sometimes referred to as the local checker is normally an external person, who does not work directly for the Company. They are often appointed by the Client and are normally native-speaker product specialists e.g distributors, agents. It is never the original translator. All revisers should have the same competencies as the translators. To fulfill the recommendations of BS EN 15038 all revisers must have some domain-specific competence in the field of translation.

#### 4.3. Reviewer

This requirement is conditional upon a review being required by the contract. A Reviewer is a third-party mother-tongue speaker of the receptor language who is appointed to read the draft translation and give feedback. He is another translator that can be involved in the translation process or correction process of a translation. We use a reviewer when a contract with a client requires this from us.

## 4.4. Proofreader

The proofreader/editor is normally chosen from within the Company. It may be another translator or simply a linguist experienced in checking texts. Rather than specific linguistic checks the proofreader checks documents for overall completeness and correct formatting. This process is normally completed after all linguistic checks have been made.



# 5. Technology

In order to maintain consistency and reduce costs to you all our translation teams use the latest 'industry-approved' language technology (e.g. CAT and term mining tools) - for instance building electronic translation databases for all technical contracts. To harmonize with our clients' approved terminology we can also leverage already existing translated material using this system and create new memory databases.

#### **5.1. Language Technology**

Language technology covers a wide range of software tools to assist translators and reviewers. It must be distinguished from machine translation which is never employed by the Company unless a mere gisting exercise is required by the client. One of the main CAT tools is translation memory or TM software which is a special linguistic database creation application that continually grows and "learns" from the translator. These are invaluable tools to help the translator maintain consistency, building up an electronic database or "TM" as it is called of terms and segments, which can be recycled for repetitive projects. For purchasers this software has the key added benefit of reducing costs for these repetitions or 'matches'. All previous translations are accumulated within the translation memory (in source and target language pairs called translation units) and re-used so that the same sentence never has to be translated twice. The more the translation memories are built up, the faster translators can work, thus accelerating delivery of translation projects and reducing costs. The translation memory software also has a whole series of additional features and functions designed to help increase productivity. Term mining tools can create glossaries and special filters can convert most file formats into tagged text allowing 'single-source' publishing.

The Company uses the industry standard TRADOS TM software as do all its translators. Using Trados the translator can open the source file and analyse it against previous similar translations so that any "100% matches" (identical matches) or "fuzzy matches" (similar, but not identical matches) within the text are instantly extracted and placed within the target file.

As the translator works through the source file, the "matches" suggested by the translation memory can be either accepted or overridden with new alternatives. If a translation unit is manually updated, then it is stored within the translation memory for future use as well as for repetition in the current text. In a similar way, all segments in the target file without a "match" are translated manually and automatically added to the translation memory.

## 5.2. Publishing Technology

Where multilingual design is required the Company has an in-house desktop publishing team that can handle most file formats ready for print or other media (e.g. In-Design, QuarkXpress, Framemaker, Pagemaker, SGML, XML).

We would normally take an existing source English desktop published file created by the client and use this as the template for the multilingual design. The Company has considerable experience in creating multilingual product insert designs (both booklet and multifold formats) to fit with the constraints of packaging whilst adhering to labelling requirements.

## 6. Staff

## **6.1. Continuing Professional Development**

All our staff are highly qualified for the particular area of the business that they work in. For project-related staff they all possess knowledge of the principals of translation and have a command of at least two foreign languages (in addition to their mother tongue). Many of our project staff who are linguists are also foreign nationals. At the Company all staff receive professional training in the various IT and language/publishing systems required to carry out the various tasks. As well as in-company training we also encourage external training for our staff as part of their personal development.

# 7. Dealing with Complaints

All client complaints are dealt with as swiftly as possible. The Company and Client may agree that any disagreements about the quality of the Work shall be referred to an independent arbitrator to be agreed by the parties as a competent person for this task. General comments about the quality of translations are not accepted but specific examples are required with suggested alternative renderings. In the unlikely event that a defective translation is proven then The Company will, where possible, correct as swiftly as possible at no extra cost. A note is then made on the *Translator's Record* of the defective translation and appropriate action taken. Many problems of inconsistency with previous translations and particularly terminology can be overcome by supply of previous translations where available and/or approval of specific term glossaries by local checkers prior to commencement of the main translation.

# Appendix A - Checklist

#### Questions related to the requirements of the BS EN 15038 standard

- 1) How do you ensure that sub-contracted input to the service you deliver will allow you to claim conformity to relevant requirements? (1.1)
- 2) How do you assess and ensure the professional competence of translators? (4.1.)
- 3) How do you assess and ensure the professional competence of revisers? (4.2.)
- 4) How do you assess and ensure the professional competence of reviewers if necessary? (4.3.)
- 5) How do you ensure that professional competences are maintained and updated
- a) by your own personnel? (6.1)
- b) by sub-contracted personnel? (1.2)
- 6) How do you ensure that your translators have adequate material resources to perform the translation project? (4.1, 5.1., 5.2.)
- 7) How would you describe your quality management system? (1.1.)
- 8) How do you ensure on a day-to-day basis that the contract/project is being performed in accordance with applicable requirements of the contract and your system? (3.2)
- 9) How do you handle your contracts/projects?

How do you:

- a) deal with enquiries? (2.1.)
- b) establish the feasibility of the contract/ project? (2.1.)
- c) issue quotations? (2.2.)
- d) conclude the contract? (2.3.)
- e) conclude subsequent deviations from the original contract. (2.3.)
- f) deal with customer communications? (3.0)
- 10) How do you manage the handling (3.2.) of
- a) contracts/projects as a whole?
- b) contact with the client during the translation process?

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- c) checking the correctness and completeness of the delivered service against the contract requirements? (3.0) (4.0)
- 11) How does the contract/project manager (3.1.)
- a) monitor and supervise the preparation process (3.2.1.) including
- i) the administrative aspects (3.2.1.) of project registration (3.2.1.) and project assignment (3.2.1.)
- ii) technical aspects (3.2.1.) of resources (3.2.1.) and pre-translation processing (3.2.1.)
- iii) linguistic aspects (3.2.1.) of source text analysis (3.2.1.), terminology work (3.2.1.) and style guide (3.2.1.)
- b) assign translators, revisers and, if necessary, reviewers ensuring
- i) they are competent (3.2.2), (3.2.3), (4.0)
- ii) have all the technical resources they need (5.1)
- iii) linguistic aspects are known?
- c) issue instructions to all parties involved in the project? (3.2)
- d) enable and monitor consistency in translation? (3.2.2)
- e) monitor and supervise the process timetable? (3.1)
- f) ensure contact is maintained with all parties involved in the process, including the client? (3.1)
- g) give clearance for delivery of the translation service? (3.2.3)
- 12) How do we
- a) monitor and verify the extent to which our translation service meets the contract requirements, our system requirements and, for the translation process, the requirements of clause 5.4 of the standard? (2.3), (2.4), (3.0)
- b) deal with complaints, correction and take corrective action with regard to defective or non-conforming services? (7.0)

#### List of formally documented procedures:

Process Stage	Document
Quotation	Project Proposal form
Contract	Service Contract form
Contract	General Terms of Business
Project Management	Project Record sheet
Project Management	Project Completion certificate
Invoicing	Project Invoice
After-sales	Client Questionnaire
Database	Translator Record