



TOP MANAGEMENT ADVISORS Ltd.

EU FUNDING PROGRAMME FOR COMPLIANCE WITH MANAGEMENT STANDARDS AND INVESTMENT IN SOFTWARE AND EQUIPMENT

The European Union and the Bulgarian Government offer financial support to organizations registered as legal entities in Bulgaria (e.g., LTD, LLC, JSC, S.A., GmbH) for **meeting the requirements of various management standards and good practices**. This programme is meant to boost the competitiveness of companies operating in Bulgaria in any sector of business and provides reimbursement of **75 % of project costs up to BGN 150,000 (ca. EUR 75,000)**.

This Programme provides for:

- ✓ **consulting services;**
- ✓ **certification by a certification body or verification by an authorized government body;**
- ✓ **purchasing of equipment or software to facilitate the standard implementation.**

Some details of the Programme are presented further down but in-depth interpretation and advice on specific cases may be obtained if you write to Vesela Mileva at iso@tma-bulgaria.com

Top Management Advisors is a leading consultancy company offering assistance in developing project proposals (the application dossier), the full scope of consulting services towards achieving compliance with some of the major standards, and specialized software for managing the documentation of the management systems.

Some answers to the questions "Do I need to certify to a management standard or What do I benefit?" are given on the next page and you may turn to us for a discussion of the subject.

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ELIGIBILITY CRITERIA FOR FINANCIAL SUPPORT

The Project Beneficiaries must be:

- ✓ legal persons or sole proprietors registered under the Trade Act or the Law for Co-operatives;
- ✓ or scientific/R & D organizations (within specified criteria);
- ✓ and have a seat in Bulgaria.

This means that **international companies registered in Bulgaria** (e.g., 100 % owned by a multinational) can benefit from this project. Also, **a public organization registered as a company** (e.g., an oncologic or psychiatric dispensary) or **a private clinic** can also apply. Organizations registered as **branches cannot apply** because they have no independent legal authority.

Specific eligibility criteria for an applicant:

- ✓ to have at least one complete financial year (2009);
- ✓ to have an annual turnover for 2009 equal to or above BGN 80,000.

Specific eligibility criteria:

- ✓ the project must be carried out only in Bulgaria;
- ✓ every project must include certification to a management standard or product compliance certification, or introduction of good manufacturing practices.
- ✓ the applicant must be capable and commit to co-finance his project.

You cannot apply only for purchasing equipment or software.

BENEFITS FROM MANAGEMENT STANDARDS IN THE PHARMACEUTICAL SECTOR

The implementation of a management standard such as ISO 9001:2008 can be a documentary exercise that leads only to another certificate on the wall and a lot of additional bureaucracy. However, *a professional consulting programme can contribute significantly to the improvement of operational efficiency, communication flow and reporting procedures*. Other standards can add value by reducing business risks and/or raising the image of the organisation.

1. Guaranteed direct access to public tenders

It is common practice for many years to require ISO 9001 certification from bidders in public tenders in all sectors. For instance, tenders for hospital supplies routinely include ISO 9001 as a preliminary requirement to all bidders. For this reason, most of the major distributors of drugs, medical devices and medical equipment are registered to ISO 9001.

It is very likely that such a requirement may be raised in tenders organised by the Ministry of Health for the supply of medication (Regulation 34) or other health-related items. In this case, a manufacturer may be forced to resort to a wholesaler if he is not registered himself.

2. Improved operational efficiency

The proper implementation of ISO 9001:2008 normally leads to more efficient allocation of responsibilities, streamlined processes and fewer mistakes, improved claims handling and faster corrective actions. In summary, *the process of preparation towards ISO 9001 certification encourages all persons involved to re-think once again how things are done in the company and how they can be improved*.

3. Reduced business risk

Preparing and getting certified to *ISO 27001:2005 for information security management* ensures that any risks of natural disasters, IT failures or human error will be reduced to a minimum.

4. Guaranteed compliance and higher image

Most of the pharmaceutical companies have an excellent reputation and are subject to audits by the local regulatory authorities and corporate audits of all kinds. Still, it may be worth covering internationally recognized specifications on top of basic legal requirement (e.g., the EU GDP Guidelines - 94/C 63/03) or meeting other relevant standards depending on the scope of business of the company.

Scope of funding

❖ Consulting services

Consulting and full support towards meeting internationally recognized management standards such as ISO 9001 (Quality Management), ISO 13485 (Medical Devices), ISO 14001 (Environmental Protection), ISO 27001 (Information Security), SA 8000 (Social Accountability) and other certifiable standards. Product certification (e.g., CE marking) or achievement of Good Manufacturing Practices are also included.

❖ Investment support

Funding for specialized software and/or equipment (including computers) which contribute to meeting the standard requirements.

❖ Certification services

This element includes certification of management standards or verification of product certification.

Deadline for submission of applications: 30 September 2010.

**For any questions, detailed explanation of benefits and preparation of applications you may turn to
Top Management Advisors at E-mail: iso@tma-bulgaria.com.**