

"Подготовка персонала по вопросам GMP для инновационного развития"

The Second
Northern Dimension Forum

Organizers:



Northern Dimension
Business Council




Saint Petersburg, 2nd March 2011



PIC/S

Pharmaceutical Inspection Co-operation Scheme



Вступление в PIC/S Прогресс и задачи

Положение дел – январь 2011 г.



Центр
европейского
сотрудничества
«Квалитех»



Европейский
центр
по качеству

АНО «Фармэкспертиза»



Pharmaceutical Inspection Co-operation Scheme

Last update 17 February 2010

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News

MoU between PIC/S and Russia / Roszdravnadzor

New

A Memorandum of Understanding (MoU) was signed in Moscow on 12 February 2010 between the PIC/S Chairman and the Head of the Federal Service on Surveillance in Healthcare and Social Development in the Russian Federation (Roszdravnadzor).

The MoU aims at facilitating Roszdravnadzor's application for PIC/S membership (and accession to PIC/S).

The MoU will only come into effect after its formal approval by the PIC/S Committee at its next meeting in Geneva on 19-20 May.



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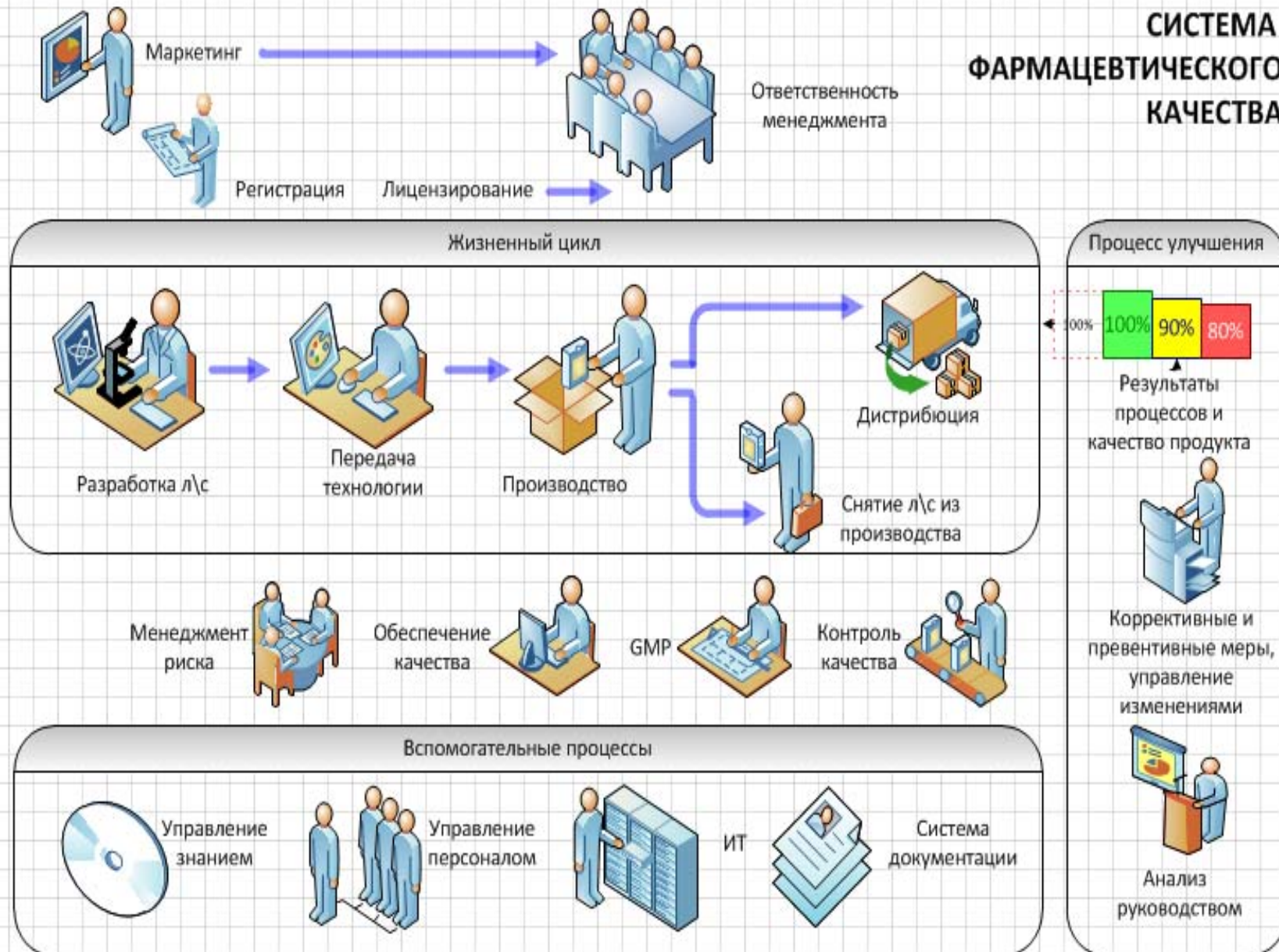
Меморандум о взаимопонимании между Федеральной службой по надзору в сфере здравоохранения и социального развития (РОСЗДРАВНАДЗОР) и Системой фармацевтических инспекторов (PIC/S) для целей присоединения к Системе фармацевтических инспекторов (PIC/S) (12 февраля 2010 г.)



Системный подход PIC/S



СИСТЕМА ФАРМАЦЕВТИЧЕСКОГО КАЧЕСТВА





Институт «уполномоченного лица»





Pharmaceutical Inspection Co-operation Scheme



Last update: 17 February 2010

Требования к институту «уполномоченного лица»

- Критерии компетентности
- Программа
- Преподаватели
- Методология обучения
- Процесс аттестации
- Признание\акредитация

Enhancement of biotechnology (Pharmaceutical engineering) curriculum at masters level in Russian Universities

Project rationale:

- To improve cooperation between Universities in the E.U. and R.F. in the field of biotechnology by assisting in the development of Master's courses in Pharmaceutical Engineering.
- The need for such a project was identified in the context of the introduction of EU compatible regulations for the pharmaceutical sector.

Shortage of trained personnel:

According to Zoya Kozlova, general director of the Pharmaceutical Recruiting Agency “Generis” (Interview October 2009) on average, there is a 30-50% shortfall of production technologists and an 80% shortfall of laboratory technologists across the 5-600 pharmaceutical producers in Russia.

Current situation:

- 50 HEIs in RF provide courses in pharmaceuticals mainly for the distribution networks.
- Qualified engineers trained in the regulatory issues, manufacturing practices and modern process methods that are needed to develop and produce modern, high technology and effective patient friendly treatments are in short supply.

Innovative medicine training in the EU:

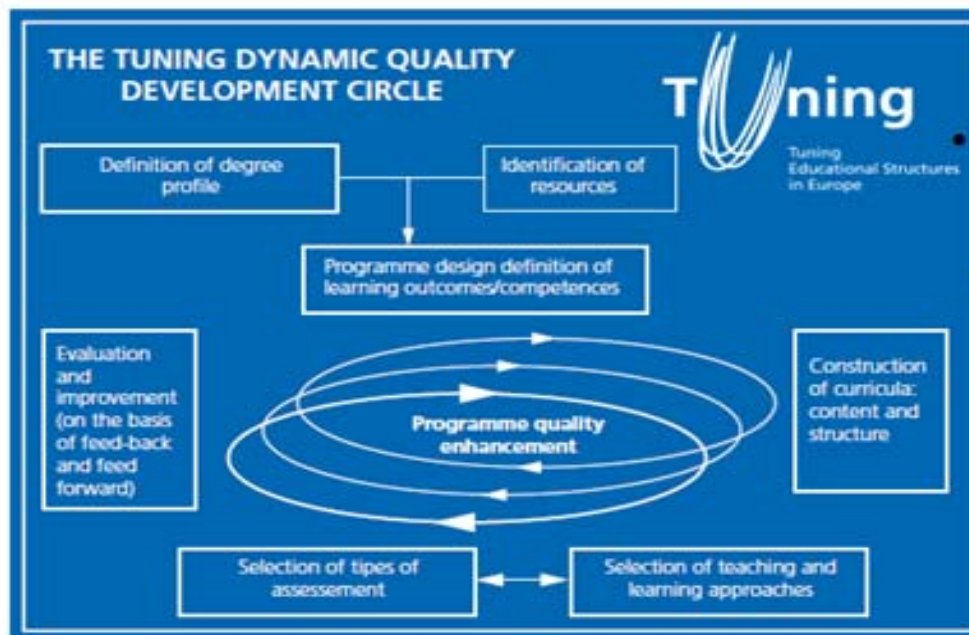
- The introduction of new techniques and methods to enhance the prediction of safety and efficacy of medicines are underpinned by better “Knowledge management” and by bridging the gaps in Education and Training.
- Several EU Higher Education bodies have moved in this direction by offering programmes in Bioscience, Biotechnology or Pharmaceutical engineering, which offer not purely the scientific disciplines such as the basics of chemistry, physics, biology and microbiology but also provide a sound knowledge of biopharmaceutical manufacturing, bioreactor design, process control and processing, metabolic engineering as well as the key regulatory aspects and a risk based approach to safety, quality and efficacy.

Specific objectives of the project:

- The project will promote the modernization, quality and relevance of higher education by developing of an inter-disciplinary and trans-disciplinary Master Programme in Biotechnology (Pharmaceutical Engineering) by the enhancement of existing courses or introducing new programmes and strengthening international cooperation aimed at providing graduates with the competences necessary for working in the modern pharmaceutical engineering environment;
- Using the approach of the EU Tuning process, the Masters curricula will be developed in line with the requirements of ECTS with the practical training of staff, development of course materials and quality assurance methods;
- A joint degree between participating Universities will be offered;
- Special attention will be paid to the employability of graduates through the direct involvement of Professional associations and regulators as stakeholders and by providing assistance in adapting the masters' programme for vocational training.

Strategy:

The project is aiming to develop a Masters Programme in Biotechnology (Pharmaceutical Engineering) using the methodology of the EU Tuning for Chemistry.



- Stakeholder involvement;
- Effective training of trainers and mobility;
- International recognition - ECTS, Tuning and Dual diplomas;
- Life long education - vocational courses;
- Wide dissemination.