

# Preparing for accreditation:

## What did we learn so far?

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# Preparing for accreditation

- 1- decision to prepare for accreditation
- 2- Which standard to choose?
- 3- First steps
- 4- Who is involved in the accreditation preparation?
- 5- How to motivate people to work in a quality management system?
- 6- Advantages/disadvantages of accreditation
- 7- Difficult issues
- 8- What would we do differently if we could start again?
- 9- Suggestions for other laboratories preparing for accreditation

## **CGPP – Centre for Predictive and Preventive Genetics**

- clinical initiative from IBMC – Institute for Molecular and Cell Biology
- provision of genetic services (outpatient clinic & diagnostic lab)
- translational research and technology transfer  
(genetic testing and counselling)
- late-onset neurological diseases and haemochromatosis
- multidisciplinary clinical team
- clinical research and support to basic biomedical research; biobank
- education and training of health professionals  
(medical genetics, psycho-social genetics)
- scheme organiser EMQN EQA SCAs

# 1- Decision to prepare for accreditation

- improve quality / performance
- lab internal organization
- Quality Manager joined the group
- Medical Geneticist joined the group



## 2- Which standard to choose?

- ISO 17025 vs ISO 15189
- ISO 9001?

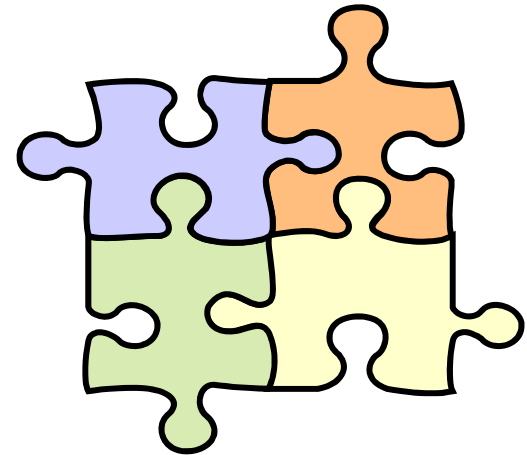
ISO 17025 - General requirements for the competence of testing and calibration laboratories

ISO 15189 - Medical laboratories — Particular requirements for quality and competence

ISO 9001 – Quality management systems - Requirements

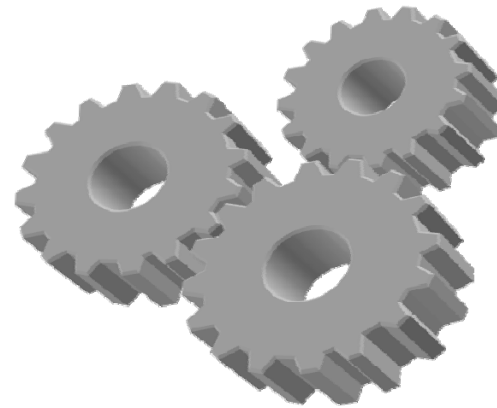
## 3- First Steps

- preliminary audit, SWOT analysis & planning
- documentation (SOPs, records)
- write what you do & do what it's written
- implementation
- internal audit
- management review



## 4- Who is involved in the accreditation preparation?

- QM full-time
- Technicians
- Top Management



## 5- How to motivate people to work in a QMS?

- motivation vs professionalism
- enthusiasm vs indifference
- resistance to change vs adaptation
- top management involvement
- short term benefits
- long term benefits



**Quality News**

**ISO 15189 : 医学实验室国际通行标准**

**摘要:**

美国(重点监护及时检验仪器)部门正忙于符合临床实验室改进(CLIA)管理法规,尤其是年月颁布的新“质量体系”要求。由健康护理组织认可联合委员会(或美国病理学家学会认可的有关部门必须始终遵循其质量标准。在美国,仅有少数医学实验室遵循国际质量管理标准。对今日国际社会—工业和制造全球化以及社会交流频繁—遵循全球通行的检验标准而实现医学结果的互认是非常重要的。(共页)

## 6- Advantages/disadvantages of accreditation

- Initial workload
- bureaucracy



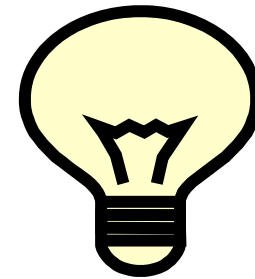
- reduction of test repetition
- quality of results & reporting
- patient & physician expectations
- non-conformities resolution
- procedures uniformisation
- internal communication

## 7- Difficult issues

- preparation for management review
- external services evaluation
  
- replacements
- supplies services
- non-conformities

## 8- What would we do differently if we could start again?

- planning laboratory layout
- automated system for quality indicators collection



## 9- Suggestions for other laboratories preparing for accreditation

- consult & involve all personnel in the process
- full-time quality manager
- EUGT quality management & accreditation workshops
- internal audit by external collaborator
- EQA Schemes
- administrative & financial independence
- evaluation of patients/clinicians satisfaction