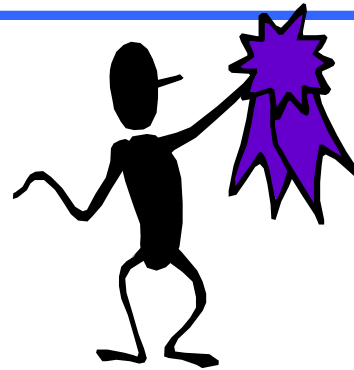


“Raw data in laboratories under quality management system and LIMS as a tool for data handling and traceability”



Imma Alsina
Quality Assurance Manager
Laboratori Agroalimentari – DARP

Ljubljana, April 19th 2006

RAW DATA

- **Raw data means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a nonclinical laboratory study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. Raw data may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.**

FDA Good Laboratory Practice Regulations 58.3

RAW DATA

- **Raw data means all original test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study. Raw data also may include, for example, photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has been recognised as capable of providing secure storage of information for a time period as stated in section 10, below.**

OCDE Section I, 2.3.7.

RAW DATA

- **RAW DATA is directly related to the measures carried out in the laboratory, the notes and any type of observations that contribute significantly to the conclusions or the final analytic result.**

RAW DATA

- **GLP:**
 - **Immediate, direct, precise and readable registration**
 - **Dated and signed**
 - **Modification without hiding precedent data**
 - **Cause of the change**
 - **Computerized data with the same approach**
 - ...

RECORDS

- **ISO17025:2005:**
- 4.12.1.1 The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of **quality and technical records**. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.
- 4.12.1.2 All records shall be legible and shall be stored and retained in such a way that they are **readily retrievable** in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. **Retention times** of records shall be established.

RECORDS

- **ISO17025:2005:**
- 4.12.1.3 All records shall be held **secure** and in **confidence**.
- 4.12.1.4 The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.

- NOTE Records may be in **any media**, such as hard copy or electronic media.

RECORDS

- **ISO17025:2005:**
- 4.12.2 Technical records
- 4.12.2.1 The laboratory shall retain records of original observations, derived data and **sufficient information** to establish an audit trail, **calibration records, staff records and a copy of each test report** or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the **identity of personnel** responsible for the sampling, performance of each test and/or calibration and checking of results.

RECORDS

- **ISO17025:2005:**
- NOTE 1 in certain fields it may be impossible or **impractical to retain records of all original** observations.
- NOTE 2 Technical records are accumulations of data (see 5.4.7) and information which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, clients' notes, papers and feedback.

DIFFERENT KIND
OF RECORDS

RECORDS

- **ISO17025:2005:**
- 4.12.2.2 Observations, data and calculations shall be **recorded at the time** they are made and shall be **identifiable to the specific task**.
- 4.12.2.3 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered along side. All such alterations to records shall be signed or initialled by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

MODIFICATION
OF RECORDS

RECORDS

- **ISO17020:1998:**
- 12.1 The inspection body shall maintain a **record system to suit its particular circumstances** and to comply with applicable regulations.
- 12.2 The records shall include **sufficient information** to permit satisfactory evaluation of the inspection.
- 12.3 All records shall be safely **stored for a specified period**, held secure and in confidence to the client, unless otherwise required by law.

INSPECTION
SERVICE

RAW DATA

- Besides the primary data, one should record in the notebook or on the "record sheet" **all the observations that are believed of to be of interest**, as well as problems that arise and an explanation of whether they have been solved.
- The data should be **written directly** in the notebook or "record sheet" as it is acquired, to avoid possible transcription errors. You should not record first on a piece of paper and, later, to transcribe it to the notebook.
- All the data should be **written in pen**. You must not use a pencil or any other type of erasable ink.

RAW DATA

- **Erasable ink** or correction liquids must not be used.
- The errors should be corrected in a way that can still be read, and the value or the correct text written in the margin. The **justification of the error** should be dated and written in the margin or at the foot of the page and it can be as simple as: "not well written", "calculation error" or "transcription error".
- **Blank pages** or substantial portions of pages without text have to be marked with a cross to ensure that they won't be used to write back dated (*posteriori*).

RAW DATA

- It is necessary to write with clear and readable letters.
- It's advisable to write using the verb in first person and in the present tense (writing down what is happening at the same moment).
- When a notebook of registration of primary data or "record sheet" of data is completed, it will be filed appropriately

NOTEBOOKS

FORMS

RECORDS

GENERATED ELECTRONICALLY

LIMS

TRANSMISSION

How improve data handling and traceability?

LIMS

Laboratory Information Management System

TRACEABILITY

- When the sample arrived
- Who received it, who accepted it and under what kind of contract conditions
- Where the sample was conserved initially
- How the sample was distributed
- Where the sample was conserved until the moment of the analysis
- If someone split the sample or sampling procedure
- What analytic procedure was followed (with detail, for example, of the conditions of use of equipment)
- Quality parameters of the analytic method used
- Technicians that carried out the analyses (training and qualifications)

Answers in LIMS

TRACEABILITY

- What reagents were used (with detail, for example, of reception date and of opening date)
- What standards / strains were used (with the supplier's certificate or all the relative information in its preparation was)
- What equipment was used (maintenance, calibration and verification)
- Who and how the specifications of the equipments, reagents, cultivation means and materials used were checked to their reception
- What mechanisms for the evaluation of the quality of the results were used
- What were the environmental conditions
- Who validated the results
- When the analysis report was published

Answers in LIMS

Characteristics of the LIMS of the Laboratori Agroalimentari - DARP

- User records: 58 with 11 types of different menus
- Determinations records: 2960
- Clients records: 427
- Cards of equipment: 1193
- Cards of chemicals: 479
- Backup space: 1.2 GB

	2003	2004	2005
Number of samples	13.670	18.367	14.999
Number of determinations	121.614	115.028	110.619

Necessary functions in a LIMS

- Management of service loads
- Traceability of data
- Management of plans/programs

Security

Flexibility

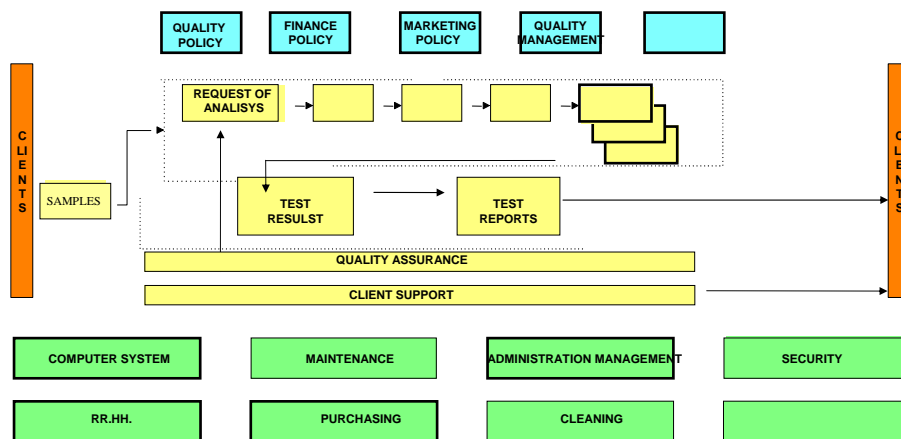
LIMS options versus ISO17025

LIMS Options	ISO17025 Requirements
<u>Management of samples</u> <ul style="list-style-type: none"> Management of Samples Information of the client and samples Chain of safekeeping Service loads Bar code Allocation of analytical procedure 	<u>Control of data and Handling of test and calibration items</u> <ul style="list-style-type: none"> Traceability Records about handling, storage and conservation of test items. A system for identifying test and/or calibration Items
<u>Menu of analysis and results reports</u> <ul style="list-style-type: none"> Crossing of results from Excel Validation of results Test report with the required information. Additional reports 	<u>Test reports</u> <ul style="list-style-type: none"> Required information : title, data of client, data of sample and univocal identification, used method, dates of reception and analysis. Changes of test reports
<u>Users profiles</u> <ul style="list-style-type: none"> Different menus with different access levels. Administrator of the system. 	<u>Control of data</u> <ul style="list-style-type: none"> Integrity of the data Verification of data

LIMS options versus ISO17025

LIMS Options	ISO17025 Requirements
<u>Management of equipment</u> <ul style="list-style-type: none"> Card of equipment Plan of calibration and maintenance History of repairs Control of manufacturer instructions 	<u>Equipment</u> <ul style="list-style-type: none"> Records of the item of equipment (Identification, manufacturer, location, instructions) Dates, results and calibration and maintenance plans. Any damage and repairs.
<u>Management of chemicals</u> <ul style="list-style-type: none"> Card of chemical Request of chemicals and stock control Control of expiry of chemical 	<u>Chemicals</u> <ul style="list-style-type: none"> Traceability Control of expiry
<u>Management of personnel</u> <ul style="list-style-type: none"> CV Training programs Organization 	<u>Personnel</u> <ul style="list-style-type: none"> Personnel list and jobs descriptions Professional qualifications Training programs

From samples acceptance to test record



Planning

- Service loads:
 - Allocation of samples by type of product

Allocation of samples by type of product

**LABORATORI AGROALIMENTARI
FULL DE RESULTATS ANALITICS**

Secció: AGRARIA Àrea: FARRATGES-FOLIARS-S. N°Regis: Data recepció o Di. Entrada a Data INICI an Data val:

Mostra de: ENSELAGE DE MADS Referència: 22-293-0122-0014 Mòdem: CAT Magatzem, Preanàlisi:

Observacions del registre: EXERCICI: INTERLABORATORI DE BIPA-FEVRER 2006 - 22 ENSELAGES

Cod.	Descripció	Àrea	Resultat	Unitat mes
03005	Preparació de la mostra	FARRATGES-FOLIARS-S.		
03010	HUMITAT (a 103°C)	FARRATGES-FOLIARS-S.		
03020	MATERIA SECA (100-H)	FARRATGES-FOLIARS-S.		
03026	pH A L'AGUA SUSPENSIO 1/5	FARRATGES-FOLIARS-S.		
03027	CENDRES	FARRATGES-FOLIARS-S.		
03030	CALCI	FARRATGES-FOLIARS-S.		
03040	FOSFOR	FARRATGES-FOLIARS-S.		
03050	MAGNESI	FARRATGES-FOLIARS-S.		
03070	MIDO	FARRATGES-FOLIARS-S.		
03051	EXTRACTE ETERI	FARRATGES-FOLIARS-S.		
03052	PROTEINA BRUTA (N%25)	FARRATGES-FOLIARS-S.		
03054	NITROGEN AMONIACAL	FARRATGES-FOLIARS-S.		
03061	PROTEINA DIGESTIBLE	FARRATGES-FOLIARS-S.		

POTENCIOMÈTRIC
 GRAVIMÈTRIA o NIR
 ABSORCIO ATOMICA / ICP o N
 COLORIMÈTRIA VISUAL o N
 ABSORCIO ATOMICA / ICP o N
 POLARIMÈTRIC
 GRAVIMÈTRIC o NIR
 VOLUMÈTRIC o NIR
 VOLUMÈTRIC
 CALCUL ARITMÈTIC

Planning

- Service loads:
 - Allocation of samples by type of product
 - Allocation of samples by analyst and method.

Elaboration of lots or series of work by technique or determination

LABORATORI AGRICOLMENTAR Llistat Fulla de Treball 24 de Febr de 2006 - 1358 Pàgina 1

Lot anàlisi: 09001 Assignat a: ALSINA I REUS, Inma

Codi Barra	Mqg	Uny	Munta de	Determinació
	0L_1465	3010205	CRNA	Horreses en vitro
	0L_1465	3010205	CRNA	Horreses en vitro
	0L_1465	3010205	CRNA	Horreses en vitro
	0L_1465	3010205	CRNA	Horreses en vitro
	0L_1465	3010205	CRNA	Horreses en vitro
	0L_1465	3010205	CRNA	Horreses en vitro

Elaboration of lots or series of work by technique or determination

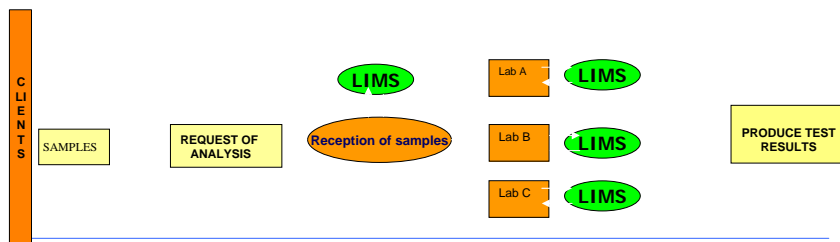
LABORATORI AGRICOLMENTAR Llistat Fulla de Treball 24 de Febr de 2006 - 1358 Pàgina 1

Lot anàlisi: 09001 Assignat a: ALSINA I REUS, Inma

Codi Barra	Mqg	Uny	Munta de	Determinació
	0L_1465	3010205	CRNA	Horreses en vitro
	0L_1465	3010205	CRNA	Horreses en vitro
	0L_1465	3010205	CRNA	Horreses en vitro
	0L_1465	3010205	CRNA	Horreses en vitro
	0L_1465	3010205	CRNA	Horreses en vitro
	0L_1465	3010205	CRNA	Horreses en vitro

Chain of safekeeping

- Each change of proprietor of the sample or subsamples is registered in the LIMS.




Chain of safekeeping

Registre	Fecha registro/Inscripción	Producto	Muestra de
06_01105	23402006	SA PRODER	Formulats fitosanitaris
06_01104	23402006	AFRICA	PROVENIDIA A
06_01102	22402006	SERVICIO DE PRODUCCIÓN RAMADERIA PISCOS de productos zootécnicos	BLAT DE MOKRO ENGILJAT
06_01102	22402006	SERVICIO DE PRODUCCIÓN RAMADERIA PISCOS	PISCO
06_01101	22402006	SERVICIO DE PRODUCCIÓN RAMADERIA PISCOS	PISCO
06_01100	22402006	SERVICIO DE PRODUCCIÓN RAMADERIA PISCOS de productos zootécnicos	PISCO
06_01099	22402006	NEDERLAND S.A.	Xocolates i derivats
06_01098	22402006	NEDERLAND S.A.	Xocolates i derivats
06_01097	22402006	NEDERLAND S.A.	Xocolates i derivats
06_01096	22402006	NEDERLAND S.A.	Xocolates i derivats

Chain of safekeeping

Registre	Secció Origen	Àrea Origen	Secció Dest	Data Origen	Hora Origen
3001/2006	DIRECCIÓ	UNITAT GARANTIA QUALITAT	NEVERA	30/01/2006	12:45
3001/2006	DIRECCIÓ	UNITAT GARANTIA QUALITAT	NEVERA	30/01/2006	12:45
3001/2006	ALIMENTÀRIA	PROD GRASSOS LLET-D	NEVERA	30/01/2006	11:15
3001/2006	DIRECCIÓ	UNITAT GARANTIA QUALITAT	NEVERA	29/04/2005	18:15


 Generalitat de Catalunya
 Departament d'Agricultura,
 Ramaderia i Pesca

Chain of safekeeping

Data Origen	Hora Origen	Secció Origen	Àrea Origen	Secció Dest	Àrea Dest
30/01/2006	12:45	DIRECCIÓ	UNITAT GARANTIA QUALITAT	ADDITUS-VITAMINES	
30/01/2006	12:45	DIRECCIÓ	UNITAT GARANTIA QUALITAT	PROD GRASSOS LLET-D	
30/01/2006	11:15	ALIMENTÀRIA	PROD GRASSOS LLET-D	UNITAT GARANTIA QUALITAT	
30/01/2006	11:07	DIRECCIÓ	UNITAT GARANTIA QUALITAT	PROD GRASSOS LLET-D	

Veure: Tots Totes les Seccions

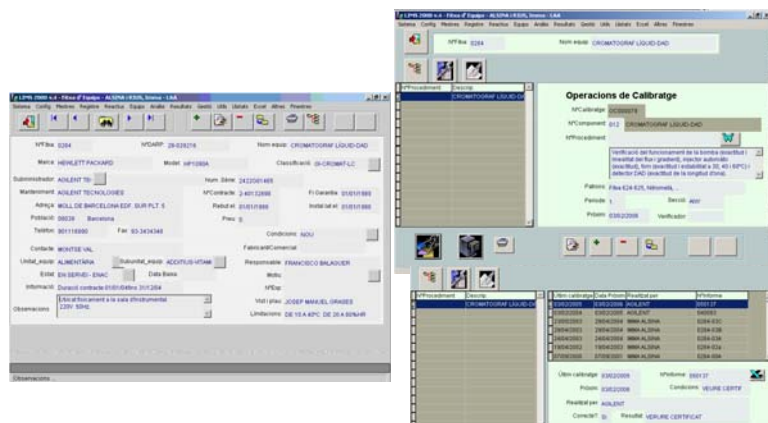
Data Origen: 30/01/2006 Hora Origen: 12:45 Usuari Origen: AULSRI
 Secció Origen: DIRECCIÓ Àrea Origen: UNITAT GARANTIA QUALITAT
 Ubicació Origen: NEVERA
 Data Dest: Hora Dest: Usuari Dest:
 Secció Dest: ALIMENTÀRIA Àrea Dest: ADDITUS-VITAMINES
 Ubicació Dest: Completat: NO


 Generalitat de Catalunya
 Departament d'Agricultura,
 Ramaderia i Pesca

Planning

- Calibration and maintenance of equipment

Calibration/maintenance planning



The screenshot displays a software interface for equipment calibration and maintenance planning. The interface is divided into several panels:

- Top-Left Panel:** Shows a detailed view of a specific piece of equipment. Key information includes:
 - Model: HP1098A
 - Brand: HP
 - Serial Number: 241220148
 - Location: LABORATORI D'ANALITICA
 - Operator: JOSEP MARCEL DANIES
- Top-Right Panel:** Titled "Operacions de Calibratge" (Calibration Operations). It displays a list of calibration records with columns for date, operator, and status. A summary table is visible below the list:

Operació	Data	Operador	Statut
24122014	2014-12-24	JOSEP MARCEL DANIES	OK
24122015	2014-12-24	JOSEP MARCEL DANIES	OK
24122016	2014-12-24	JOSEP MARCEL DANIES	OK
24122017	2014-12-24	JOSEP MARCEL DANIES	OK
24122018	2014-12-24	JOSEP MARCEL DANIES	OK
- Bottom-Left Panel:** Shows a list of equipment items with columns for ID, name, and location.
- Bottom-Right Panel:** Shows a summary of calibration operations, including the date, operator, and status.

Calibration/maintenance planning

LABORATORI AGRICOLAMENTARI
ALBINA I REUS, TARRAGONA

Calendari de Calibracions- 2006

Secció: 27622906
Àrea: Pag: 1

Equip	Descripció	NºComp.	NºPtes.	Responsable	Gen	Feb	Mar	Abr	Mai	Jun	Jul	Ag	Sep	Oct	Nov	Dic
0214	BALANÇA GRANATARI	021		USQI MANEL ARAGAY												
0215	BALANÇA GRANATARI	021		USQIMONTE DE GRATOVEL												
0242	TURBOVAP	020		PILAR RODRIGUEZ	X											
				HERNANDEZ												
				MANEL PEREZ												
				IL PEREZ												
				MANEL PEREZ												
				NURIA CANET												
				HERNANDEZ												
				HERNANDEZ												
				CORI DALMAU												
				RODRIGUEZ	X											
				DE DALMAU												
				GARCIA												
				GARCIA												
				DOLORES GISPERT												
				DOLORES GISPERT												
				BENOVIETA ANDREU												
				RODRIGUEZ	X											
				GARCIA												
				IL PEREZ												
				LUIS CAMMUCHO												

Planning

- Calibration and maintenance of equipment
- Inventory of reagents or chemicals



Inventory of chemicals

The left screenshot displays a chemical entry form for 'ALCOHOL METILIC per HPLC'. It includes fields for 'Marca' (PAIRREAC), 'Quantitat' (0.00), and 'Contingut' (1 L). The supplier is listed as 'PAIRREAC QUIMICA, S.A.'. The right screenshot shows a table with columns for 'Data', 'Quantitat', and 'Preu'. It lists several entries with dates like '2012/08/08' and quantities like '12.00'.

Inventory of chemicals

LABORATORI AGRICOLMENTARI 24 de Patrim de 2008 - 14/25

Inventari Reactius

Pàgina | 1

USUARI	Reactiu	Nom	Quantitat	Preu	Valor	
	5115	COURE E ACETAT 1-INDRAY	PRO	PAIRREAC 141201.1210	0.00	24.57
	5887	SEPTIMS PER VIALS HEND-SPACE 20	DOMA I TERPOL	TEBROFORO 201-021	0.00	110.20
	4714	ACETANILIDA	PA	NEROK 100011.0000	0.00	37.75
	5601	SULFONAMIDOMAN	JP	PAIRREAC 121408.1210	0.00	41.48
	5684	PICNOLIS SULFAT	PA	PAIRREAC 121408.1211	0.00	17.85
	4736	ACETONITRIL FOR ANALITIC DE PESTI	P	SCHALLAU AC201000	0.00	16.00
	4738	ACETONITRIL	PRE-ACS	SCHALLAU AC201000	0.00	16.00
	4739	ACETONITRIL HPLC purissimum	PRE-ACS	PAIRREAC 121408.1211	0.00	52.20
	5481	PLUM ABSORBT per AA	HCNEX	QUIMVITA 48821	0.00	18.21
	5565	POTASSIUM per AA	ELUTIT	EMTER 2106.0010	0.00	15.84
	4738	ACID ACETIC 30%	JP	NEROK 5110	0.00	5.00
	5565	POTASSIUM per AA	HCNEX	EMTER 2106.0011	0.00	15.84
	5648	ACID ACETIC HPLC	PRE-ACS	SCHALLAU AC201000	0.00	16.00
	4732	ACID ACETIC HPLC	PA	SCHALLAU AC201000	0.00	8.95
	5077	CANOLLES PER VIALS DE HEND-SPACE	SI-ACS	TEBROFORO 201-021	0.00	30.43
	5647	COLUMBES CASI PER VIALS D'ANALITIC	PA	WATERS 18471002	0.00	200.00
	5565	POTASSIUM SULFAT	PA	PAIRREAC 121408.1211	0.00	16.41
	5736	TAMPON pH 4.00	HCNEX	QUIMVITA 48821	0.00	8.00
	5565	POTASSIUM SULFAT	PA	PAIRREAC 121408.1211	0.00	16.30
	5618	SODIUM SULFAT	PA	SCHALLAU 56102	0.00	16.35
	5407	PLACIDES POLIMERIA 117254	21 Japane	NEROK 5000	0.00	93.80
	4734	ACID CLORIDIC 3 N	HCNEX	NEROK 50005.0000	0.00	8.42
	5450	PERMANG	PRE	SCHALLAU P1120	0.00	40.50
	5443	PERMANGANAT	PRE	SCHALLAU P100500	0.00	19.20
	5441	PERMANG	PRE	QUIMVITA 48811	0.00	33.00
	5438	PERMANGANAT	PRE	SCHALLAU P100500	0.00	7.80
	4736	ACID CLORIDIC 3N	HCNEX	QUIMVITA 48811	0.00	9.00
	5617	ZINC SULFAT MONOHIDRAT	PRE	QUIMVITA 48800	0.00	22.74
	5622	SODIUM CARBONAT	PA	SCHALLAU 56101	0.00	7.33
	4809	ACID ETILDIAMINOTETRAACETIC per HPLC	PRE-ACS	NEROK 50040.0000	0.00	80.20
	5244	COUMINES PER VIALS DE HEND-SPACE	PRE	WATERS 18471001	0.00	172.00
	4813	ACID FOSFORIC	PRE	QUIMVITA 48847	0.00	41.85
	4804	ACID LACTIC	PRE	QUIMVITA 48842	0.00	41.30
	4808	AMONIUM SULFAT 18000	PA	PAIRREAC 131130.1211	0.00	23.80

Continua a la pagina següent.

Planning

- Calibration and maintenance of equipment
- Inventory of reagents or chemicals
- Control of expiry of chemicals

Control of chemicals to expiry

LABORATORI AGROALIMENTARI
 ALSINA I RIUS, Imma
 REACTIVOS A CADUCAR



24/02/2006

Ubicació	Reactiu	Nom	Qualitat	Exist.	Cad.	15 dies	1 mes	2 mesos	3 mesos
C 014	4704	ACID CLORHIDRIC 1N (BAKER	VALORACI	1.0	1.0	0.0	0.0	0.0	0.0
D 051	5737	TAMPO pH=4.01	REAGENT	1.0	0.0	1.0	0.0	0.0	0.0
E 037	4903	AIGUA OXIGENADA 30%	PA	5.0	5.0	0.0	0.0	0.0	0.0
F 010	4971	AMONI FOSFAT dibasic	RPE-ACS	1.0	0.0	1.0	0.0	0.0	0.0
F 073	5515	CICLOHEXA ANALISI PESTI	PA	6.0	3.0	0.0	0.0	0.0	3.0
G 023	5619	SODI BICARBONAT	RPE-ACS	3.0	0.0	0.0	0.0	1.0	0.0
G 033	5638	SODI CLORUR	PA	2.0	0.0	0.0	0.0	0.0	2.0
I 40	5440	n-PENTA	RPE	8.0	2.0	0.0	0.0	0.0	0.0
K 24	5236	FORMALDEHID 35-40%	PA	2.0	2.0	0.0	0.0	0.0	0.0
M 19	4785	ACID CITRIC monohidrat	PA	1.0	0.0	1.0	0.0	0.0	0.0
O 107	5708	VIALS CHROMACOL Ref 00-	CROMATOG	10.0	0.0	0.0	0.0	0.0	1.0
P 24	5606	SILICONA pasta A	QP	2.0	1.0	0.0	0.0	0.0	0.0

Security

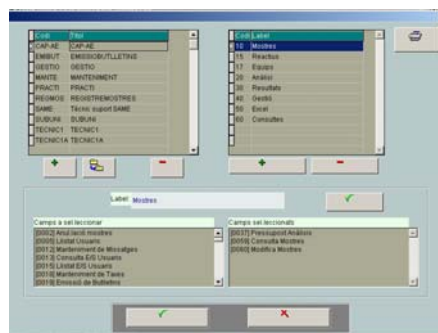
- A LIMS must guarantee that the stored data is safe.
- A key piece in the management of the traceability must be a incorruptible system.

Integrity

Robustness

Security

- 1 system administrator and different levels of access.



Security : validation of LIMS

Design control

Functional control

Operational control

Integrity of data

Security : validation of LIMS

- Validation of operational and functional design



Security : validation of LIMS

- The validation of a LIMS must incorporate these two aspects robustness and integrity of the data and can be made by choosing a data set, that we will adopt like patterns and verifying its stability in time.

Continuous Validation

Operational Control

Statistical studies

- It is a powerful tool of a LIMS that allows flexibility in the management and the use of the data stored in the data base.
- The data stored in the LIMS can be transferred to Excel spreadsheets .

LIMS evolution in the Laboratori Agroalimentari - DARP

1997



- Operative processes: From the reception of the sample to the issuing of the results report
- Support processes: Module of reagents and module of equipment.
- Strategic processes: Management of the quality system

2006

Changes in processes



Changes in LIMS

Conclusions

- It allows better planning of work.
- It facilitates the registration of primary data and its traceability in general.
- It saves time, it reduces the tasks of administration and management of the information.
- It reduces errors in the registration of samples and the global management of data. It facilitates the unequivocal numeration of samples.
- It automatically makes the tasks of generation of test reports, receipts, labels, etc. that fulfill the requirements of the norm.

Conclusions

- Control and manage the warehouse of reagents and chemicals, standards and expendable equipment.
- It allows a controlled and defined access to the information.
- It controls and it manages the calibration plan, verification and maintenance of the instrument equipment of the laboratory.
- It offers a great security and speed in information searches.

Conclusions

- LIMS is an indispensable tool for the management of the laboratory in ISO17025 framework.