
GROUPE LABEXA
BIOLOGIE MEDICALE

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Standardizing and Harmonization of Three Laboratories in France Using Lean, Analytics, and Quality Management Systems

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Presented by Jean-Philippe GALHAUD, Director of Medical Affairs, LABEXA Group

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Labexa Group introduction

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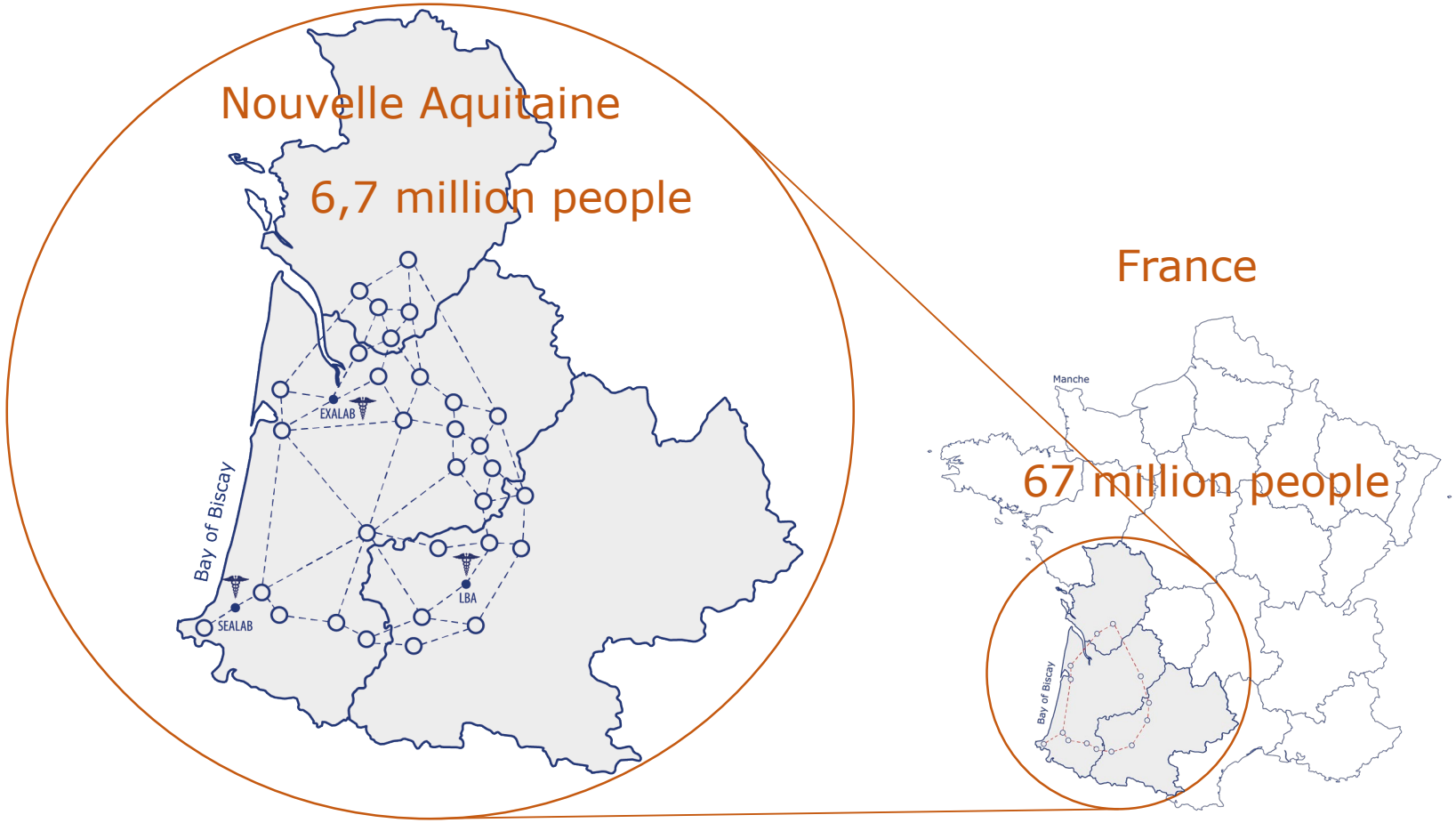
Group Labexa on the Map and in Numbers



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Founded in 1922

#1 Laboratory chain in Nouvelle Aquitaine

79 laboratories (Blood Collection Points, BCPs)

Yearly turnover of LABEXA is over 100 million €uros

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The Group in Brief

LABEXA Group

Independent, Privately owned Medical Biology Group with a strong regional footprint.
3 subsidiaries
with **Common Values** and a **Unified Production Concept**.

Tubes per **Day**	8 200	3 300	3 000	**14 500**
3 LBMs (Laboratoire de Biologie Médicale)	EXA LAB BIOLOGIE MEDICALE	SEA LAB BIOLOGIE MEDICALE	LBA LES BIOLOGISTES ASSOCIES	**Total**
Tubes per **Year**	2 500 000	1 000 000	900 000	**4 400 000**

These numbers correspond to more than 2.5 million patients per year (~10 000 patients/day)

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Laboratory Profile

* Given numbers correspond to the results of 2018

	Tests per 2018 year	Total, %	Exalab	LBA	Sealab
Chemistry	11 800 000	64,3	6 500 000 (55%)	2 600 000 (22%)	2 700 000 (23%)
Hematology	1 705 000	9,3	950 000 (56%)	355 000 (21%)	400 000 (23%)
Immunochemistry	1 650 000	9,0	950 000 (58%)	350 000 (21%)	350 000 (21%)
Coagulation	910 000	5,0	650 000 (71%)	110 000 (12%)	150 000 (16%)
Serology	580 000	3,2	400 000 (69%)	75 000 (13%)	105 000 (18%)
Capillary	365 000	2,0	200 000 (55%)	90 000 (25%)	75 000 (21%)
Immunohematology	235 000	1,3	150 000 (64%)	35 000 (15%)	50 000 (21%)
Special Chemistry	225 000	1,2	135 000 (60%)	40 000 (18%)	50 000 (22%)
Special Immunochemistry	90 000	0,5	55 000 (61%)	10 000 (11%)	25 000 (28%)
Molecular Biology	62 500	0,3	50 000 (80%)	5 000 (8%)	7 500 (12%)
Special Coagulation	41 000	0,2	40 000 (98%)	-	1 000 (2%)
Others	286 500	1,6	195 000 (68%)	49 500 (17%)	42 000 (15%)
TOTAL	**18 342 000**		**10 495 000 (57%)**	**3 766 500 (21%)**	**4 080 500 (22%)**

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Total Head Counts

	Production + BCP *			
	Exalab	**Sealab**	**LBA**	**Total**
Lab specialists ("Biologiste médical")	59	24	20	17
Lab Technicians	194	85	50	329
Nurses	66	11	11	88
Receptionists	106	28	37	171
Couriers	24	6	15	45
Cleaning staff	10	7	9	26
Lab Assistants	5	0	0	5
Others (HR, Accounting, etc.)	31	7	7	45
Total	**495**	**168**	**149**	**812**

2018 numbers

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WHAT, WHY, WHO, HOW

Question:

Merge 3 independent subsidiaries

→ 3 labs are accredited (norm 15189 v2012)

EXA LAB Biologie Médicale

cofrac Accréditation n°8-1371
Listes des sites et portées disponibles sur www.cofrac.fr

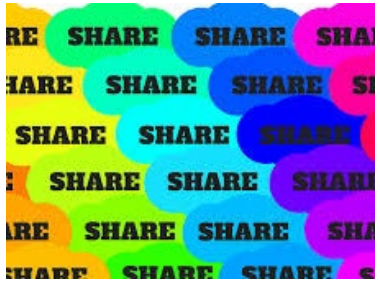
LBA LES BIOLOGISTES ASSOCIÉS

cofrac Accréditation n°8-3008
Listes des sites et portées disponibles sur www.cofrac.fr

SEA LAB Biologie Médicale

cofrac Accréditation n°8-3703
Listes des sites et portées disponibles sur www.cofrac.fr

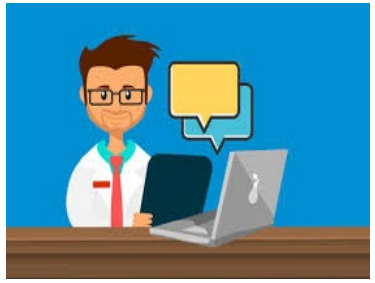
SAME ENVIRONMENT



- **decrease of reimbursements**
- **need for new investments :**

  (new technology, IT, accreditation etc…)
- **sharing same values**

EXPECTATIONS



- **Reduce costs :** economies of scale
- **Add clinical value :** pay for performance vs pay for service
- **Improve medical service** for patients and physicians
  (creation of new department : Auto Immunity)
- **Reinforce our group**
- **Reference brand for Laboratory medicine**

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WHO

EXA LAB Biologie Médicale

LBA LES BIOLOGISTES ASSOCIÉS

SEA LAB Biologie Médicale

ISO 15189 ACCREDITATION

MEDICAL LABORATORY

- **Same requirements but different accreditations :**
  - accreditation ref. numbers (1371,3008,3703)
  - % of accredited exams
  - calendars are different (different dates of audit visits)
  - To sum up: different levels of progression

- **Different Information Systems :**
  - 4 different LIS
  - 2 quality software programs
  - 3 HR software packages
  - 3 metrology software programs

EXA LAB Biologie Médicale
LBA LES BIOLOGISTES ASSOCIÉS
SEA LAB Biologie Médicale

- **Different analyzers from different** suppliers

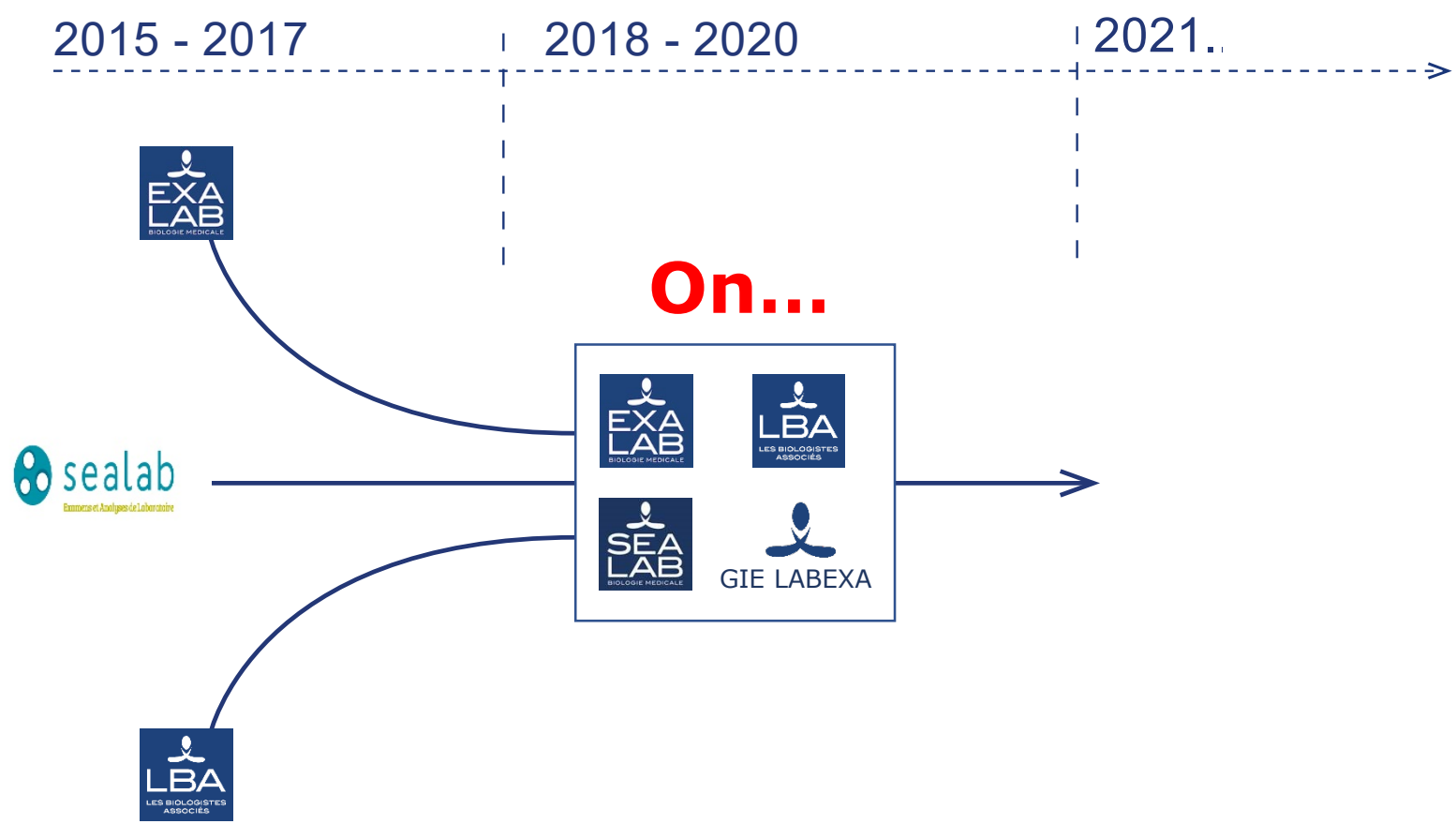
- **Different EBITDA**

To initiate the harmonization, we started by

creating a holding company

to manage the subsidiaries in the same way

BRAND UNIFICATION



based on accreditation 100 %

(obligatory in France) NF EN ISO 15189 v2012:

« The current international norm relates to medical laboratories that develop their quality management system (QMS) and assess their own skills »

→ Instead of enduring the requirements of the ISO 15189 norm, we have used accredidation to better manage our labs by changing minds and creating a « quality mindset » in our company.

BEFORE

How was Quality perceived?

I wrote what I did and I described everything in big bulky procedures.

Quality management was felt as a new layer of requirements; employees could have the feeling of a constraint

Steering committees looked more at the additional costs than the possible benefits it could bring to the business

NEW MINDSET

- **Quality management with Process Approach:**
  Quality is **intregrated**.

  I use quality management as a tool to better manage my company with clear key processes with a good follow up.

  This is the **Process Approach**.

Overall management and quality management joined forces and supported each other

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Labexa Group Process Approach

PROCESS APPROACH

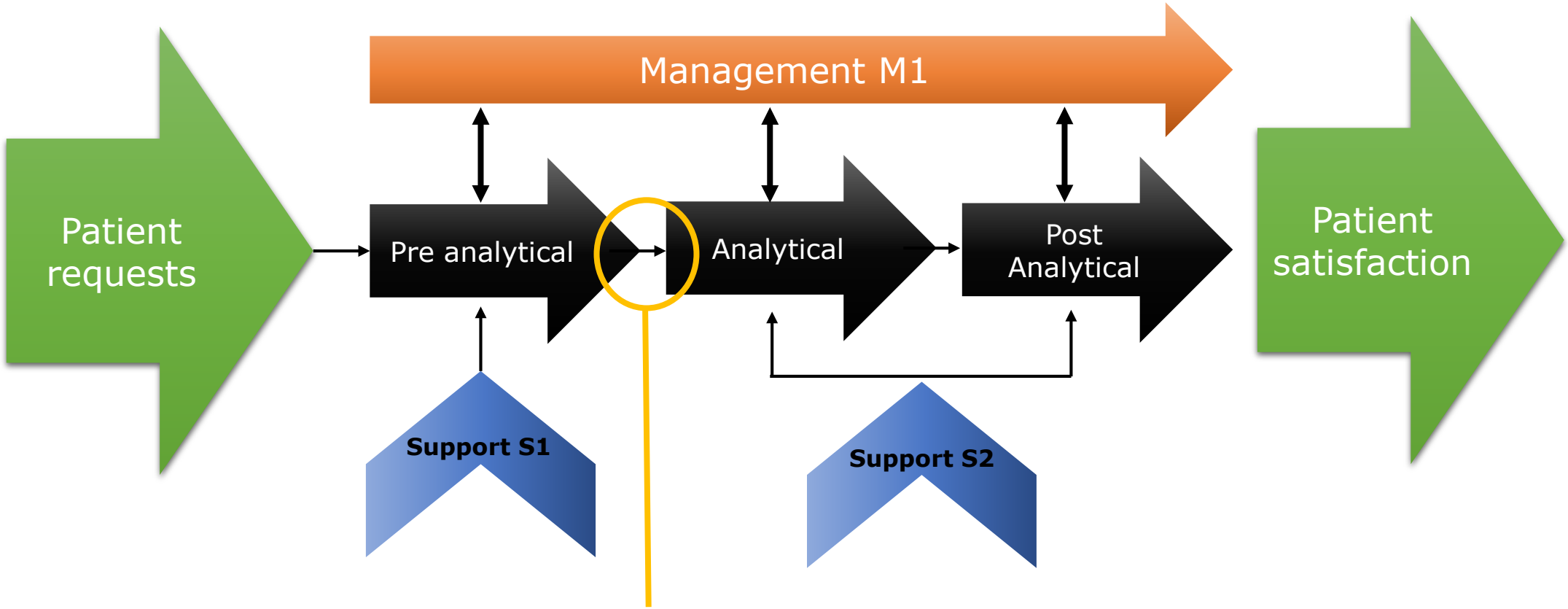
Lean Process Approach:

Normative requirement that can bring improvement.
(ISO 9001 integrated since v 2012 in ISO 15189)

Reminds the company that the main goal for all activities inside a laboratory is to satisfy our customers : patients, prescribers etc…

It’s about defining how to mobilise « Know-how » and integrated skills in the running of the laboratory.

Lean Process Approach : main principles



Added value is passed on to the next stage

PROCESS APPROACH

In LABEXA :
Harmonization =
The same Process Approach for our 3 subsidiaries

Never forget **the goal**

Add value

Patient and customer **satisfaction**

Strong commitment to **health care improvement**

The patient
is at the heart of the LABEXA project

PROCESS APPROACH

Set up of lean Process Approach in LABEXA group :

Group processes replacing subsidiary processes.

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So as to improve organization with harmonization,

sharing experiences and skills

PROCESS APPROACH

Process Mapping :

Easy way to present our Process Approach

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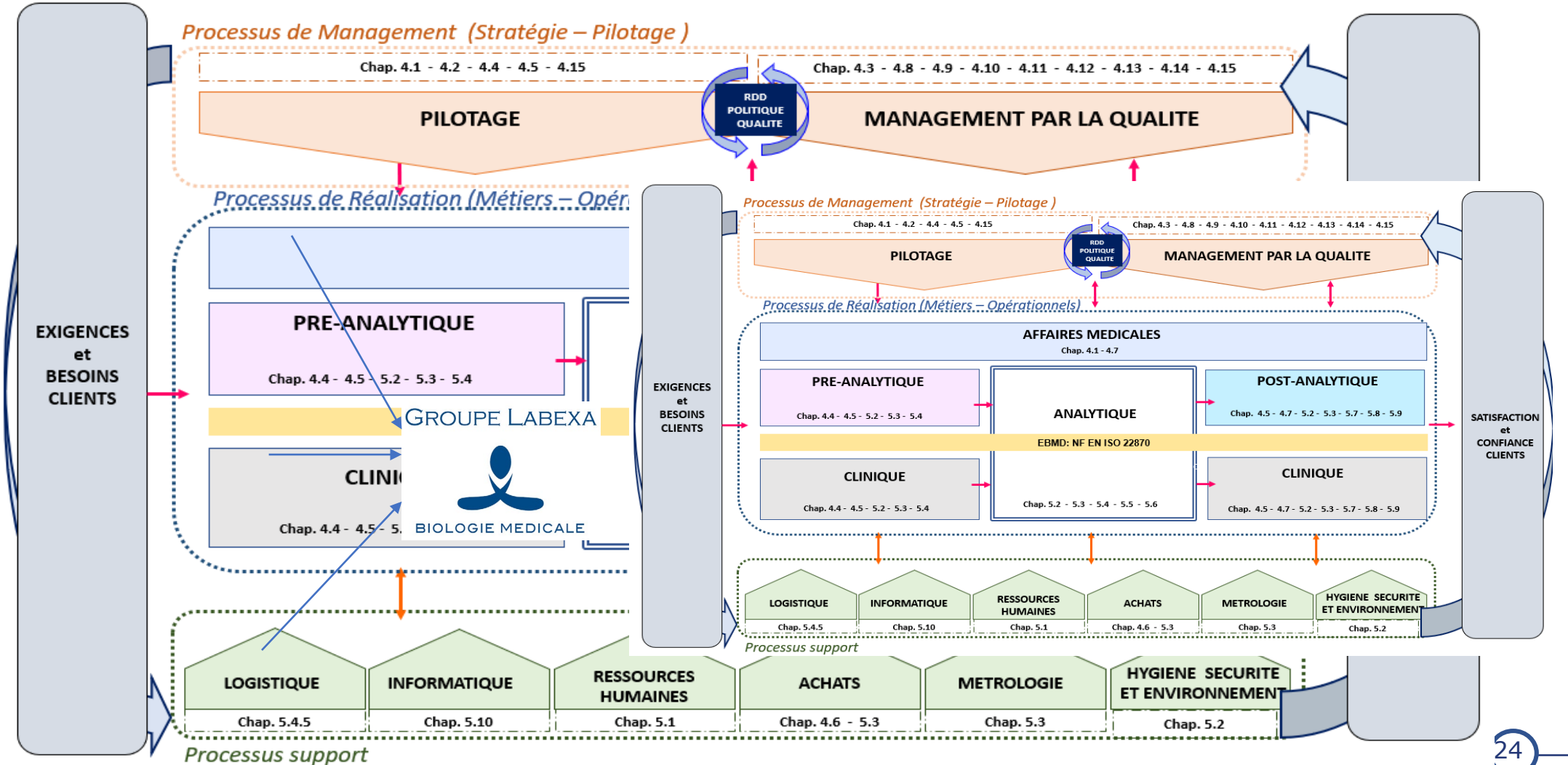


LABEXA group Process Approach : **Expected benefits**

Detailed & easy to read working plan for group activities

Clear vision of the interaction between all the activities

Identification of the critical points and risks

LABEXA group Process Approach : **Expected benefits**

Continuous improvement as a work principle

Conditions to allow everyone to situate themselves within the organization and better understand the aims of their activities

Responses to user needs and satisfaction to all customers

Better control of the internal structure already implemented

PROCESS APPROACH

LABEXA group Process Approach : **Step by step**

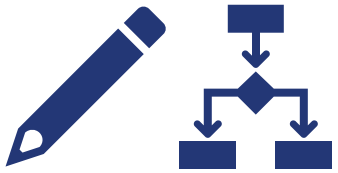
Make a T0 of processes in each subsidiary

Identify and choose the group process

Identify the group process pilot and deputies for each subsidiary

PROCESS APPROACH

LABEXA group Process Approach : **Step by step**



Write and describe each group process

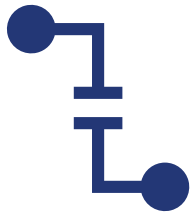
Adapt organization by adjusting resources and information needed for good process running

Drive by follow-up: measure and analyze processes to reach our goal ; continuous improvement (PDCA)

PROCESS APPROACH

Description of each process

Identify customers and their expectations

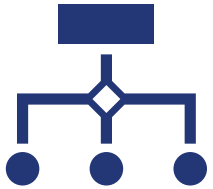


Determine inputs and outcomes

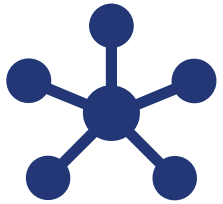
Create the ID card of the process

PROCESS APPROACH

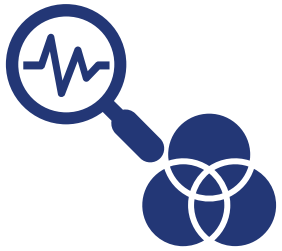
Description of each process



Describe every activity of the process



Determine sequence and interactions of the different processes



Choose criteria and methods to ensure control and check the process with « Risk Analysis »

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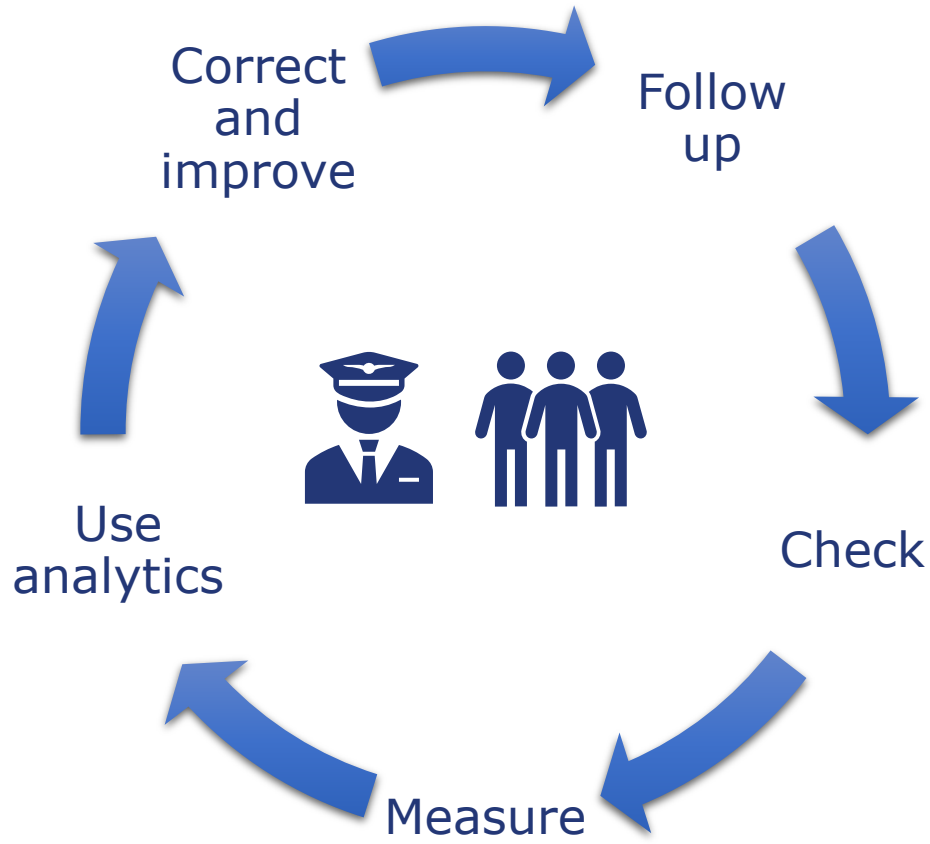
PROCESS APPROACH



DRIVE THE PROCESS

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EXA LAB Biologie Médicale

LBA LES BIOLOGISTES ASSOCIÉS

SEA LAB Biologie Médicale

Each deputy :

- check opposite trends
- define the levers to correct unsatisfactory trends and gaps

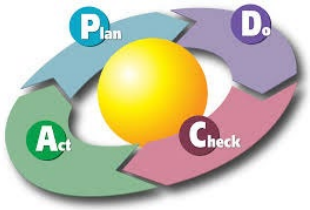
Define Quality Indicators : Group QI & sometimes subsidiary QI (depending on the risk analysis)

PROCESS APPROACH

ENSURE PROCESS CONTROL

Monitor processes through surveillance audits

Use analytics to evaluate the impact of non conformity forms



Analyze the impact of NC subsidiaries

Enforce preventive (PA) and corrective (CA) actions at group and subsidiary levels to obtain the set results and continuous improvement of different processes

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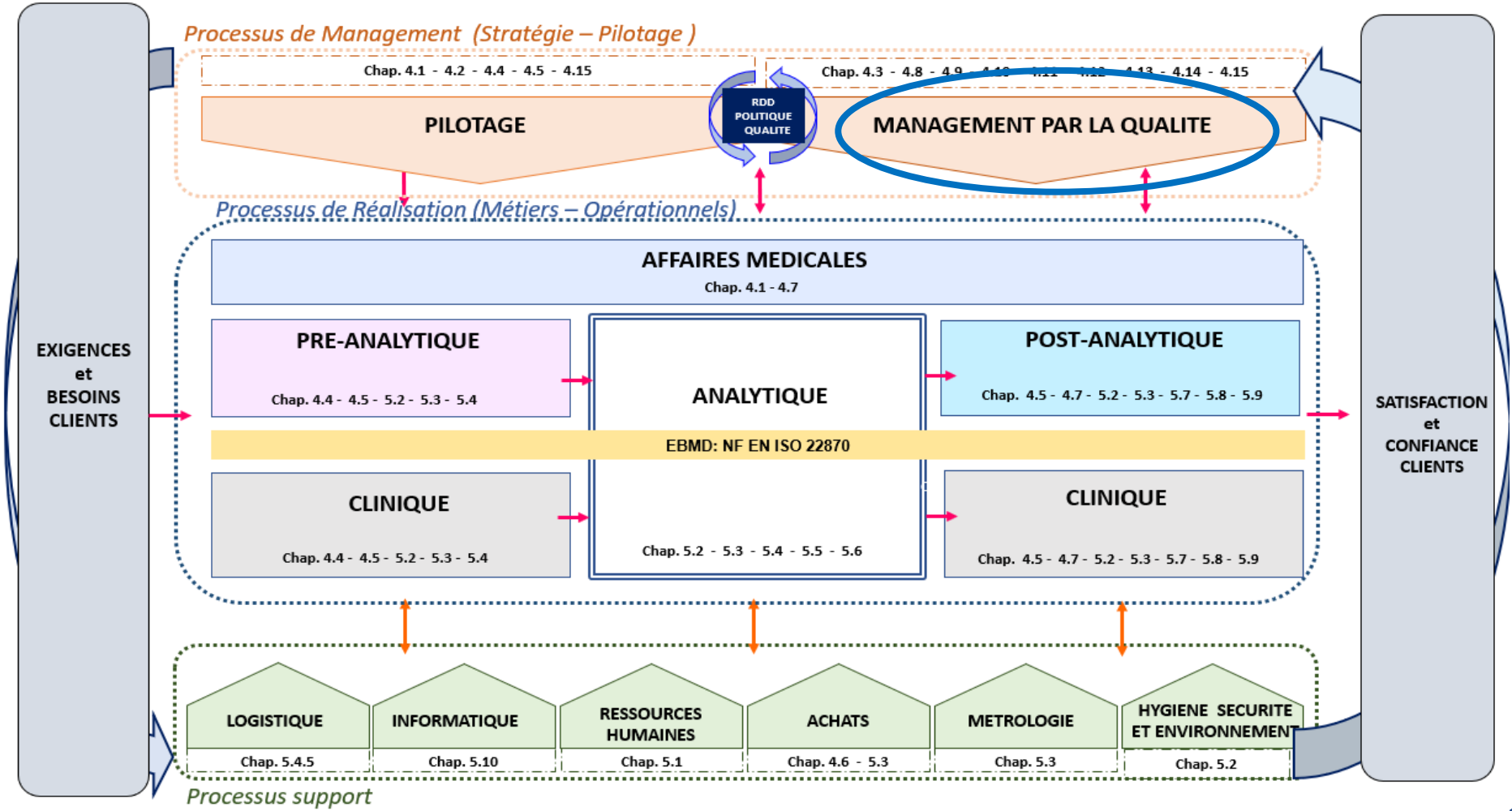
PROCESS APPROACH

EXAMPLE PROCESS ID CARD



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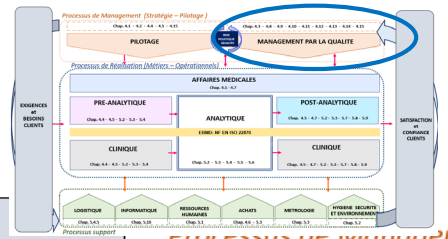
PROCESS APPROACH

EXAMPLE PROCESS ID CARD



Processus de Management (Stratégie – Pilotage)

Chap. 4.1 - 4.2 - 4.4 - 4.5 - 4.15

PILOTAGE

RDD POLITIQUE QUALITE

Chap. 4.3 - 4.8 - 4.9 - 4.13 - 4.14 - 4.15

MANAGEMENT PAR LA QUALITE

Processus de Réalisation (Métiers – Opérationnels)

AFFAIRES MEDICALES

Chap. 4.1 - 4.7

EXIGENCES et BESOINS CLIENTS

PRE-ANALYTIQUE

Chap. 4.4 - 4.5 - 5.2 - 5.3 - 5.4

ANALYTIQUE

POST-ANALYTIQUE

Chap. 4.5 - 4.7 - 5.2 - 5.3 - 5.7 - 5.8 - 5.9

EBMD: NF EN ISO 22870

CLINIQUE

Chap. 4.4 - 4.5 - 5.2 - 5.3 - 5.4

Chap. 5.2 - 5.3 - 5.4 - 5.5 - 5.6

CLINIQUE

Chap. 4.5 - 4.7 - 5.2 - 5.3 - 5.7 - 5.8 - 5.9

SATISFACTION et CONFIANCE CLIENTS

LOGISTIQUE

Chap. 5.4.5

INFORMATIQUE

Chap. 5.10

RESSOURCES HUMAINES

Chap. 5.1

ACHATS

Chap. 4.6 - 5.3

METROLOGIE

Chap. 5.3

HYGIENE SECURITE ET ENVIRONNEMENT

Chap. 5.2

Processus support

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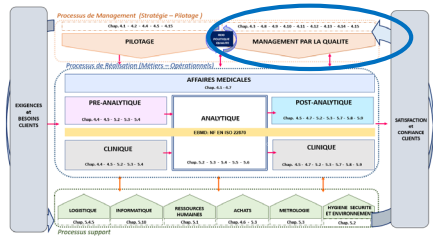
PROCESS APPROACH

EXAMPLE PROCESS ID CARD



PROCESSUS DE MANAGEMENT : MANAGEMENT PAR LA QUALITE

1 group pilot **1 deputy for each subsidiary**

Pilote groupe	**Myriam LABAN**
Pilotes filiales	**EXALAB** = Stéphanie DEMARS COLLE - **LBA** = Agnès FORTIER – **SEALAB** = Anne VAN HAMME
Clients	Tout le personnel
Finalité / Valeur ajoutée	S'approprier une démarche dynamique pour mettre en œuvre, évaluer et améliorer en continu l'efficacité du système de management de la qualité et une gestion efficiente des risques.
Procédures générales associées	LABEXA-PRO-018 « Management par approche processus » LABEXA-PRO-008 « Gestion et maitrise de la documentation » LABEXA-PRO-002 « Non-conformité réclamations » LABEXA-PRO-003 « Gestion des audits » LABEXA-PRO-014 « Gestion des risques » LABEXA-PRO-016 « Revue de Direction » LABEXA-PRO-010 « Gestion de la portée flexible » LABEXA-PRO-020 « Gestion de la sous-traitance »
Indicateurs Thèmes	Cf. LABEXA-INS-111 « Indicateurs qualité »

DONNEES D'ENTREE	ACTIVITES	DONNEES DE SORTIE
•Revue de Direction validée et diffusée •Politique qualité et objectifs validés et diffusés •Ressources attribuées •Clients internes et externes •Communication ascendante et descendante	•Gestion des 4 GED et veille documentaire •Veille réglementaire et normative •Bilan des non conformités, réclamations, actions correctives et actions préventives •Réalisation du planning d'audits •Gestion des risques •Préparation de la revue de Direction de l'année •Revue des indicateurs et de leur pertinence •Réalisation des enquêtes de satisfaction •Recueil des suggestions du personnel •Accompagner et aider l'ensemble des départements et des collaborateurs dans le déploiement du SMQ •Gestion de la portée flexible	•Clients satisfaits •Amélioration continue du SMQ et de la qualité des soins prodigués aux patients •SMQ efficient et conforme à la politique et aux objectifs qualité définis par la direction •Flux d'informations maitrisé

Process quality indicators allow to monitor and to act as soon as malfunctions are detected

Activities are described in group process

→ a risk analysis is performed on processes

In each process, and in each risk analysis, mean of controlling can be different and adapted to each subsidiary

Les dispositions relatives à la validation biologique des examens sont décrites dans EXA_QUAL-PRO-010 « Validation biologique des analyses ».

Les dispositions relatives à la validation biologique des examens sont décrites dans PG-MU1-001 « Validation biologique »

Les dispositions relatives à la validation biologique des examens sont décrites dans PT-MU1-001 « PR Validation biologique des résultats d'examens ».

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PROCESS APPROACH

Management by Quality = Unified QMS

7M Check list for risks and activities

Man
Machine
Material
Method
Milieu = Environment = Mother Nature
(the original 5M method)

Management
Monitoring

Risk and activities identified as for the group

Way of controlling is different depending on the subsidiary

7M	Activités (cf. Fiche processus)	Risques identifés	EXALAB		LBA		SEALAB	
			Moyens de maitrise	AMDEC (oui/non)	Moyens de maitrise	AMDEC (oui/non)	Moyens de maitrise	AMDEC (oui/non)
Main d'œuvre								
Méthodes								
Milieu								
Matériel								
Matières								
Management								
Money								

Risk management :
based on a common model, but identifying different means of control by subsidiary

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PROCESS APPROACH

Management by Quality = Unified QMS

Risk management based on a common model, but identifying different means of control by subsidiary

ACTIVITIES (cf. Fiche processus)	7M	Identified risks	EXALAB		LBA		SEALAB	
			MEANS OF CONTROL	FMECA (Y/N)	MEANS OF CONTROL	FMECA (Y/N)	MEANS OF CONTROL	FMECA (Y/N)
PHLEBOTOMY	MAN	Unskilled laboratory staff	Trained, qualified and authorized personnel	NO	Trained, qualified and authorized personnel	NO	Trained, qualified and authorized personnel	NO
		Uninformed external nurses	Nurses provided with an instruction manuel on phlebotomy rules and process	NO	Nurses provided with an instruction manuel on phlebotomy rules and process	NO	Nurses provided with an instruction manuel on phlebotomy rules and process	NO
		Accidental Blood Exposure (ABE)	Trained, qualified and authorized personnel	NO	Trained, qualified and authorized personnel	NO	Trained, qualified and authorized personnel	NO
	METHOD	Missing phlebotomy procedure	LABEXA-PRO-012	NO	LABEXA-PRO-012	NO	LABEXA-PRO-012	NO
	MILIEU ENVIRONMENT **MOTHER NATURE**	Patient confidentiality issues in phlebotomy rooms	Soundproof and secure phlebotomy rooms Audit compliant Exalab sites	NO	Soundproof and secure phlebotomy rooms Audit compliant LBA sites	NO	Soundproof and secure phlebotomy rooms Audit to be done for some SEALAB sites	YES
		Unsatisfactory metrology monitoring	Better thermometer monitoring in storage rooms	NO	Better thermometer monitoring in storage rooms	NO	Better thermometer monitoring in storage rooms	NO

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PROCESS APPROACH

Management by Quality = Unified QMS

Risk management based on a common model, but identifying different means of control by subsidiary

ACTIVITIES (cf. Fiche processus)	7M	Identified risks	EXALAB		LBA		SEALAB	
			MEANS OF CONTROL	FMECA (Y/N)	MEANS OF CONTROL	FMECA (Y/N)	MEANS OF CONTROL	FMECA (Y/N)
PHLEBOTOMY	MACHINE	unsuitable equipment with ABE risk	Needles with safety systems Adapted Trash can and gloves First aid kit available	**NO**	Needles with safety systems Adapted Trash can and gloves First aid kit available	**NO**	Needles with safety systems Adapted Trash can and gloves First aid kit available	**NO**
		Out-of-stock of phlebotomy devices	Stock management Cf. LABEXA-PRO-036 Regularly controlled stock	**NO**	Stock management Cf. LABEXA-PRO-036 Regularly controlled stock	**NO**	MaitStock management Cf. LABEXA-PRO-036 Regularly controlled stock "	**NO**
		Suppliers' recommendations are not followed	Specification sheet management. Medical devices vigilance data base and medical diagnostic devices vigilance data base.	**NO**	Specification sheet management. Medical devices vigilance data base and medical diagnostic devices vigilance data base.	**NO**	Specification sheet management. Medical devices vigilance data base and medical diagnostic devices vigilance data base.	**NO**
	MATERIAL	Non compliant sample (wrong tube, insufficiently filled up, …)	Trained, qualified and authorized staff Phlebotomy instruction manual at disposal Regular training for provided for nurses	**NO**	Trained, qualified and authorized staff Phlebotomy instruction manual at disposal Regular training for provided for nurses	**NO**	Trained, qualified and authorized staff Phlebotomy instruction manual at disposal Regular training for provided for nurses	**NO**

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PROCESS APPROACH

Management by Quality = Unified QMS

Risk management based on a common model, but identifying different means of control by subsidiary

ACTIVITIES (cf. Fiche processus)	7M	Identified risks	EXALAB		LBA		SEALAB	
			MEANS OF CONTROL	FMECA (Y/N)	MEANS OF CONTROL	FMECA (Y/N)	MEANS OF CONTROL	FMECA (Y/N)
PHLEBOTOMY	MANAGEMENT	No steering committee for pre-analytical process	Group leader appointed and subsidiaries leaders appointed. Regular process review. Process Quality Indicators follow up.	**YES**	Group leader appointed and subsidiaries leaders appointed. Regular process review. Process Quality Indicators follow up.	**YES**	Group leader appointed and subsidiaries leaders appointed. Regular process review. Process Quality Indicators follow up.	**YES**
	MONEY	Overuse of blood sample tubes	Respecting instruction manual of phlebotomy. Quality indicators monitoring. Implementation of a group production process.	**NO**	Respecting instruction manual of phlebotomy. Quality indicators monitoring. Implementation of a group production process.	**NO**	Respecting instruction manual of phlebotomy. Quality indicators monitoring. Implementation of a group production process.	**NO**

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PROCESS APPROACH

Management by Quality = Unified QMS

FMECA (Failure Modes, Effects and Criticality Analysis)

		ANALYSES DE RISQUES																RECOMMANDATIONS		
Mode de défaillances = 7M	**Potential failure modes = activities**	**Potential effect(s) of failure = risk**	**Severity EXALAB**	**Severity LBA**	**Severity SEALAB**	**Potential cause(s) of failure**	**Occurence EXALAB**	**Occurence LBA**	**Occurence SEALAB**	**Current process control**	**Détectabilit é EXALAB**	**Détectabilit é LBA**	**Détectabilit é SEALAB**	**CRITICALITY EXALAB**	**CRITICALITY LBA**	**CRITICALITY SEALAB**	**Action taken**	**Porteur de l'action**	**Completion date**
MANAGEMENT	Activités de PRELEVEMENT: Absence de pilotage du processus pré-analytique Absence de management du processus Défaillance du processus	Processus défaillant Difficulté à harmoniser les procédures et les compétences	**5**	**5**	**5**	Changement de pilote régulier sur chaque filiale. Manque de stabilité NO prise en compte de problématiques filiales mal connues et non remontées au niveau du groupe	**5**	**5**	**5**	Contrôle réalisé par le département qualité avec suivi d'indicateurs	**5**	**5**	**5**	**125**	**125**	**125**	Désigner un pilote du processus par filiale Mettre en place des réunions mensuelles du processus avec les 4 pilotes	Pilote du processus groupe	01/10/2019
METHOD	Confidentialité des salles de prélèvement	Salle de prélèvement ne répondant pas aux exigences de confidentialité (locaux non adaptés, pas de fermeture de porte, …)			**10**	Locaux non conformes			**2**	Visite de chaque site Audit de site			**5**			**52**	Vidéo de chaque site afin de visualiser les locaux non visités Harmonisation des audits	Ingénieur PROCESS Directrice Qualité	01/10/2019 30/11/2019

In LABEXA :

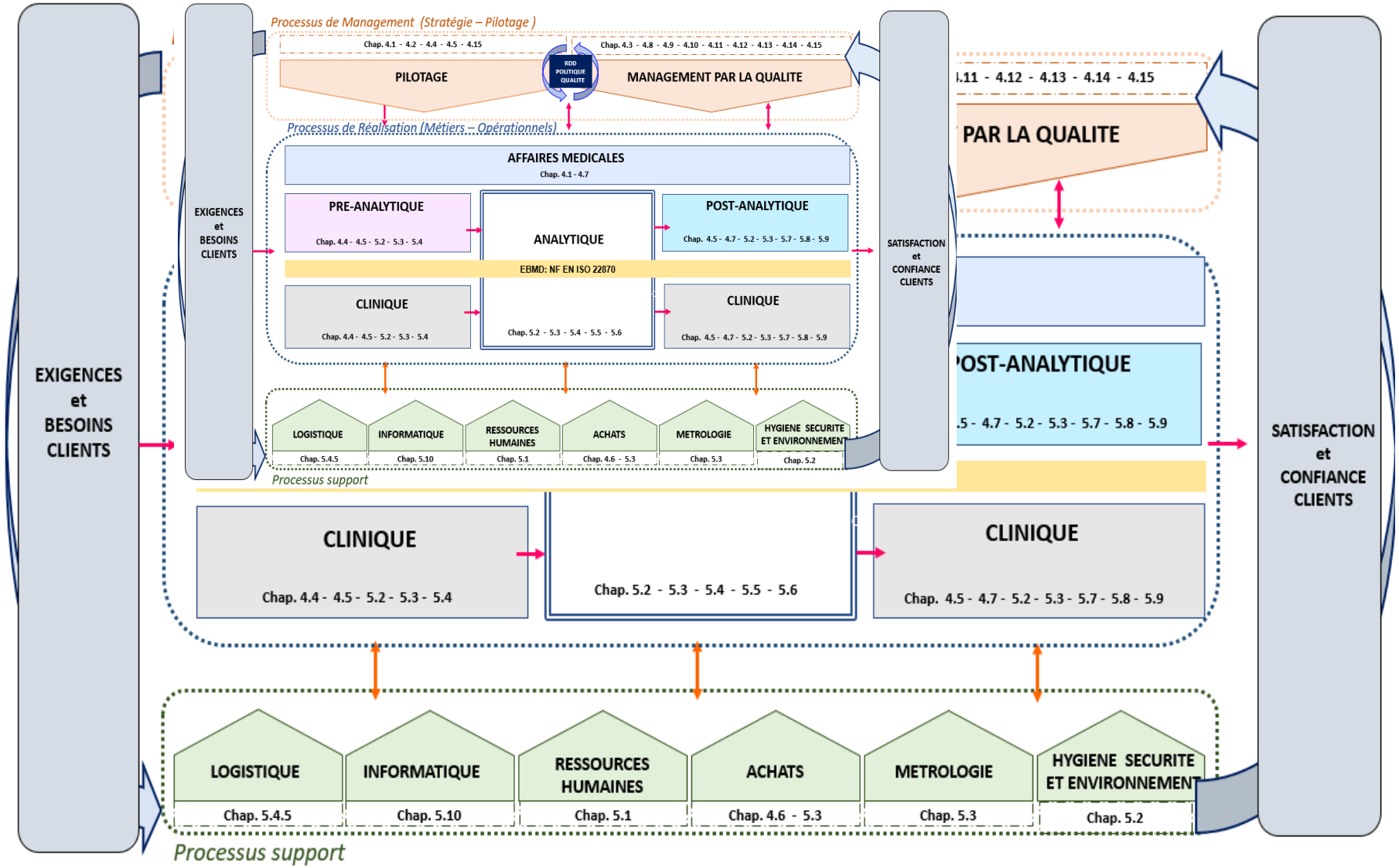
One very tangible example of application

The Unified Production Concept

GROUPE LABEXA

BIOLOGIE MEDICALE

UNIFIED PRODUCTION CONCEPT
LINKS WITH PROCESS APPROACH



GROUPE LABEXA

BIOLOGIE MEDICALE

UNIFIED PRODUCTION CONCEPT
LINKS WITH PROCESS APPROACH

STANDARDIZED PRE-ANALYTICAL

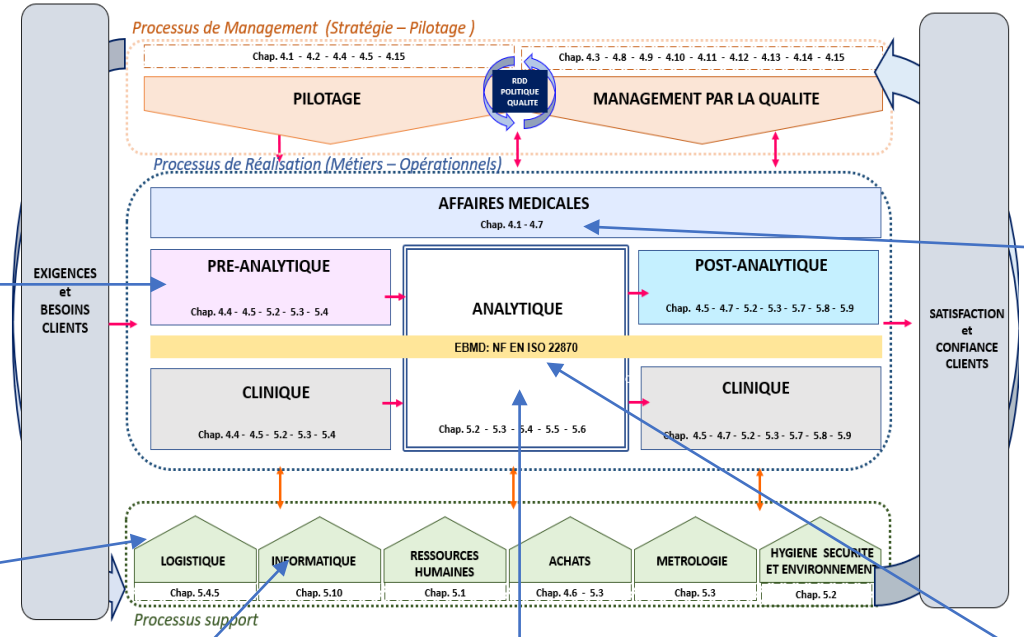
- Same treatment in each BCP
- Unique serum tube = less references
- Simplified logistic
- Reduce number of tubes = simplify production process
- Simplify inventory

A PERFORMING LOGISTIC

- Frequent tours = smoothing the activity
- Less tubes
- Adapted to environnment (city or countryside)

A RANDOM BARCODE

- 12 digits
- Without any visible logic
- Recognized on each analyzer
- Allows subcontracting
- Simplify treatment



AN ADAPTED SORT LOGIC

- Adapt flows to optimize work in corelab
- Smooth workflow for PULL logic (continuous tube arrival)
- Generate consistent workflows
- Smaller team but more committed
- Adapt timetable and schedule for all the team

A UNIFIED CATALOG

- Logical classification of unique assay
- Scientific coherence
- Get conforming samples
- Base for IS unification
- Allows to unify pre and post analytical phases
- The reference, impossible to modify

EFFECTIVE CORELABS

- Less corelabs
- Less analyzers
- Less QC
- Stand alone sorters (instead track)
- Horizontal unification: same analyzers in each corelab, connected (MW software) and correlated
- Optimize auto-validation
- Back up between the corelab (not internal)
- Simplify quality procedures
- 100 % accredited
- promote POCT devices

GROUPE LABEXA

BIOLOGIE MEDICALE

UNIFIED PRODUCTION CONCEPT

A UNIFIED CATALOG

- Logical classification of unique assay
- Scientific coherence
- Get conforming samples
- Base for IS unification
- Allows to unify pre and post analytical phases
- The reference, impossible to modify

Unified for all labs

Main Catalogue

* * *

Department	Subdepartment	Test type	UC_Test_Name	Simple test/Launched test	Biomaterial	Production Test Type	Technique	Condition Test	Condition	PP Index	*Invoice Index*	*Test Code*	*Unique Assay Code*	Family_COFRAC
Biochemistry	Biochemistry	1	Creatinine		Serum	10				1		1001	1001	
Biochemistry	Biochemistry	1	Creatinine		Heparin Plasma	10				1		1006	1001	
Biochemistry	Biochemistry	1	Creatinine		Urine 24	10				1		1002	1001	
Biochemistry	Biochemistry	3	Creatinine Clearance		Serum + Urine 24	30				**0**		1003		
Biochemistry	*Biochemistry*			Creatinine	Serum	10				1		*1001*	1001	
Biochemistry	*Biochemistry*			Creatinine	Urine 24	10				1		*1002*	1001	
Biochemistry	Electophoresis	3	Electrophoresis		Serum	20				1		1003	1003	
Biochemistry	Biochemistry			Total Protein	Serum	10				1		*1004*	1004	
Biochemistry	Biochemistry	1	Total protein		Serum	10				1		1004	1004	
Hematology	Hematocytology	4	NFP		EDTA Sang Total	20				1		2001		
Hematology	Hematocytology			NU	EDTA Sang Total	20						*2002*	2002	
Hematology	Hematocytology			FO	EDTA Sang Total	20						*2003*	2003	
Hematology	Hematocytology			PLQ	EDTA Sang Total	20						*2004*	2002	
Hematology	Hematocytology	3	Retic		EDTA Sang Total	20				1		2005	2005	
Hematology	Hematocytology			NU	EDTA Sang Total	20						*2002*	2002	
Hematology	Hematocytology	5	NU		EDTA Sang Total	20				0		2002	2002	
Hematology	Hematocytology	5	FO		EDTA Sang Total	20				0		2003	2003	
Hematology	Hematocytology	1	PLQ		EDTA Sang Total	20				1		2004	2002	
Hematology	Hematocytology	1	Hematocryte		EDTA Sang Total	20				1		2005	2002	
Immunology	Viral Serology	1	HIV AB Screen		Serum	10				1		3001	3001	
Immunology	Viral Serology	2	Hiv Confirmation		Serum	10				1		3002	3002	
Immunology	Viral Serology							HIV AB Screen	Positive			*3001*		
Molecular Biology	Molecular Biology	1	CHLAMYDIA TRACHOMATIS : GENOME (DETECTION QUALITATIVE)		Urine					1		4001	4001	
Molecular Biology	Molecular Biology	1	CHLAMYDIA TRACHOMATIS : GENOME (DETECTION QUALITATIVE)		Vaginal Swab					1		4002	4001	
Molecular Biology	Molecular Biology	1	CHLAMYDIA TRACHOMATIS : GENOME (DETECTION QUALITATIVE)		Urethral Swab					1		4003	4001	

Logical classification for each test
Analytical informations
Production informations
Pre-analytical informations

GROUPE LABEXA

BIOLOGIE MEDICALE

UNIFIED PRODUCTION CONCEPT

STANDARDIZED PRE-ANALYTICAL

- Same treatment in each BCP
- Unique serum tube : less references
- Simplified logistic
- Reduce number of tubes : simplify production process
- Simplify inventory

LBM	EXALAB	LBA	SEALAB	
LBM	EXALAB	LBA	SEALAB	
 CITRATE	2	2	2	
 Additifs		0.109 M		
E.D.T.A	2	2	2	
 Additifs		K2		
 FLUORE	1	1	1	
 HEPARINE +/- (GEL) CLINIQUE	2	1	1	
 SST 7ml	1	1	1	
SEC	1	1	1	
Situation UNIFORMISEE	**9**	**8**	**8**	
TOTAL	**22**	**10**	**15**	**LABEXA**
NB of tubes (per year)	3 490 700	653 600	1 305 700	5 450 000
With unique SST2	2 816 878	653 600	927 487	4 397 965
Tube savings	- 673 822	0	-378 213	**-1 052 035**

GROUPE LABEXA

BIOLOGIE MEDICALE

UNIFIED PRODUCTION CONCEPT

EFFECTIVE CORELABS

- Less corelabs
- Less analyzers
- Less QC
- Stand alone sorters (instead track)
- **Horizontal unification**: same analyzers in each corelab, connected (MW software) and correlated
- Optimize auto-validation
- Back up between the corelab (not internal)
- Simplify quality procedures
- 100 % accredited
- promote POCT devices

2017	CORELAB	MICROBIO	ANALYZERS
EXALAB	10	3	289
LBA			
SEALAB			

09/2019	CORELAB	MICROBIO	ANALYZERS
EXALAB	5	1	151
LBA			
SEALAB			

GROUPE LABEXA

BIOLOGIE MEDICALE

Labexa Biomarkers in 11/2016

BECKMAN COULTER

Abbott

SIEMENS

Roche

BIOMÉRIEUX

DiaSorin

Stago

Werfen

		EXALAB				LBA		SeaLab	
		LE HAILLAN	St Aug	Blaye	MDM	**NERAC**	Condom	**BAYONNE**	Aressy
Biochimie	**CPK CREATINE PHOSPHOKINASE**								
Biochimie	**CREATININE**								
Biochimie	**CREATININE ENZYMATIQUE**								
Biochimie	**CRP**								
Biochimie	**Delta4 androsténédione**								
Biochimie	**FER**								
Biochimie	**FERRITINE**								
Biochimie	**FR**								
Biochimie	**GAMMA GLUTAMYL TRANSFERASE (γGT)**								
Biochimie	**GENTAMICINE**								
Biochimie	**GLUCOSE**								
Biochimie	**HAPTOGLOBINE**								
Biochimie	**IMMUNOGLOBULINE A (IgA)**								
Biochimie	**IMMUNOGLOBULINE G (IgG)**								
Biochimie	**IMMUNOGLOBULINE M (IgM)**								
Biochimie	**LACTATE**								
Biochimie	**LACTICODESHYDROGENASE (LDH)**								
Biochimie	**LIPASE**								
Biochimie	**LITHIUM**								
Biochimie	**MAGNESIUM**								
Biochimie	**MICROALBUMINURIE**								
Immuno/Séro	**AC HBC**								
Immuno/Séro	**AC HBC IgM**								
Immuno/Séro	**AC HBS**								
Immuno/Séro	**ACCP**								
Immuno/Séro	**ACE**								
Immuno/Séro	**ACTH**								
Immuno/Séro	**AFP**								
Immuno/Séro	**AG HBS**								
Immuno/Séro	**Antistreptolysines**								
Immuno/Séro	**ATG (Ac anti-thyroglobuline)**								
Immuno/Séro	**ATPO**								
Immuno/Séro	**BNP**								
Immuno/Séro	**BW**								
Immuno/Séro	**CA 125**								
Immuno/Séro	**CA 153**								
Immuno/Séro	**CA 199**								
Hemostase	**DDIM**								
Hemostase	**activité anti-Xa**								
Hemostase	**Facteur II**								

GROUPE LABEXA

BIOLOGIE MEDICALE

Labexa Biomarkers in 09/2019

		EXALAB		LBA	SeaLab
		LE HAILLAN	St Aug	NERAC	BAYONNE
Biochimie	CPK CREATINE PHOSPHOKINASE				
Biochimie	CREATININE				
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Biochimie	FR				
Biochimie	GAMMA GLUTAMYL TRANSFERASE (γGT)				
Biochimie	GENTAMICINE				
Biochimie	GLUCOSE				
Biochimie	HAPTOGLOBINE				
Biochimie	IMMUNOGLOBULINE A (IgA)				
Biochimie	IMMUNOGLOBULINE G (IgG)				
Biochimie	IMMUNOGLOBULINE M (IgM)				
Biochimie	LACTATE				
Biochimie	LACTICODESHYDROGENASE (LDH)				
Biochimie	LIPASE				
Biochimie	LITHIUM				
Biochimie	MAGNESIUM				
Biochimie	MICROALBUMINURIE				
Immuno/Séro	AC HBC				
Immuno/Séro	AC HBC IgM				
Immuno/Séro	AC HBS				
Immuno/Séro	ACCP				
Immuno/Séro	ACE				
Immuno/Séro	ACTH				
Immuno/Séro	AFP				
Immuno/Séro	AG HBS				
Immuno/Séro	Antistreptolysines				
Immuno/Séro	ATG (Ac anti-thyroglobuline)				
Immuno/Séro	ATPO				
Immuno/Séro	BNP				
Immuno/Séro	BW				
Immuno/Séro	CA 125				
Immuno/Séro	CA 153				
Immuno/Séro	CA 199				
Hemostase	DDIM				
Hemostase	activité anti-Xa				
Hemostase	Facteur II				

BECKMAN COULTER

Abbott

SIEMENS

Roche

BIOMÉRIEUX

DiaSorin

Stago

Werfen

After horizontal unification

GROUPE LABEXA

BIOLOGIE MEDICALE

Executive Board Commitment

GROUPE LABEXA

BIOLOGIE MEDICALE

INVOLVEMENT OF THE BOARD OF DIRECTORS

SET UP A UNIFIED GOVERNANCE

Shared values from all the leaders : independence, efficiency, high performance

Patient is at the heart of our daily commitment

Governance flow chart is now part of the statute of each subsidiary

GROUPE LABEXA

BIOLOGIE MEDICALE

INVOLVEMENT OF THE BOARD OF DIRECTORS

ALLOW RESOURCES

Material resources

Human resources

Needed for development of an organization and a management answering to requirements of NF EN ISO 15189, considering the needs and demands of customers (patients, physicians, hospitals, authorities)

GROUPE LABEXA

BIOLOGIE MEDICALE

INVOLVEMENT OF THE BOARD OF DIRECTORS

STRONG COMMITMENT OF THE BOARD OF DIRECTORS

They decided together to go for the quality policy

Same team quality for application in each subsidiary

Policy and goals give the group the main direction for the organization, the expected results and the required resources to realize the objectives

Based on the results of risk analysis, the Board of Directors expresses how the satisfaction of the customers demand is at the heart of its concerns.

GROUPE LABEXA

BIOLOGIE MEDICALE

Involvement of the Board of Directors

Group quality management cannot be done without a strong commitment from all the Board Directors

GROUPE LABEXA

BIOLOGIE MEDICALE

Constraints and challenges

Constraints

Different quality softwares (2)

Documentation heterogenous, non unified, need to be simplifie

Harmonize skills

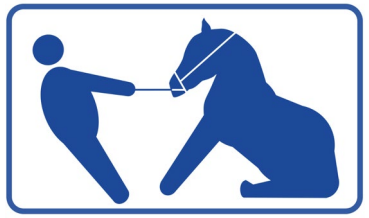
Different LIS (4)

Data security and protection between subsidiaries (GDPR rules…)

GROUPE LABEXA

BIOLOGIE MEDICALE

Challenges



Changes : resistance to change

Distance between BCPs and corelabs

Communication : adapt communication tools

Tools : to adapt to new organization

GROUPE LABEXA

BIOLOGIE MEDICALE

Results and achievements

Results and achievements

Process Approach organization is the cornerstone of all activities in LABEXA Group enabling :

- Performance to be driven ;
- Organization to be better controlled ;
- Transversality to be defined for all activities in the company

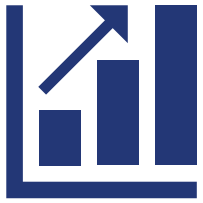
GROUPE LABEXA

BIOLOGIE MEDICALE

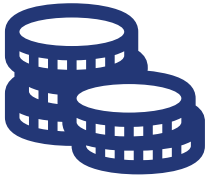
Results and achievements

REALIZED OUTCOMES

Make the whole process more suitable to satisfy our customers (patients – physicians…)



Optimize the distribution of resources available



Optimize costs

GROUPE LABEXA

BIOLOGIE MEDICALE

Results and achievements

REALIZED OUTCOMES

Increase the involvement of all actors

Reduce stress and tensions due to partitioning by subsidiary

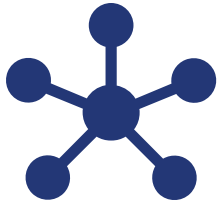
Develop communication (inter and intra branch)

GROUPE LABEXA

BIOLOGIE MEDICALE

Results and achievements

REALIZED OUTCOMES



Formalize the interactions between each process

Control risk management through risk analysis

Define priorities

Increase and improve responsiveness on actions to run

GROUPE LABEXA

BIOLOGIE MEDICALE

Conclusion

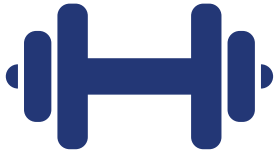
GROUPE LABEXA

BIOLOGIE MEDICALE

Results and achievements

Achieving the goal

Now, our system is



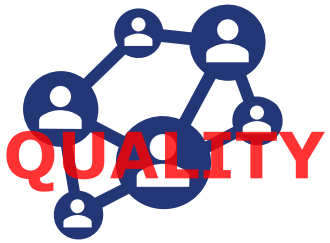
STURDY

100 % accreditable for each subsidiary

Teams are involved in a continuous improvement process

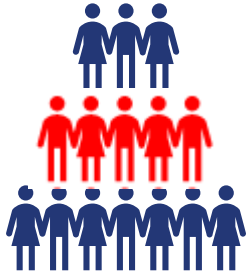
Results and achievements

Achieving the goal



Quality has become a corporate culture

We are ready for internal and/or external merger



We are ready for quality management with a smaller team

GROUPE LABEXA

BIOLOGIE MEDICALE

Quality team of LABEXA Group

Thanks !

Any questions ?

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