



ON-SITE CALIBRATION



Pharma

“Regular calibration by Flexim experts is quick and easy. It ensures the compliance of our measuring devices without any disruption to production.”

*David Holton,
Metrology Manager,
LFB.*



Measuring Task

Pharmaceutical water flow measurement for the calibration of flow meters in production areas

In line with its international growth and development, LFB is developing its production capacity with a next-generation facility. This new facility should triple LFB's overall capacity for producing plasma-derived medicinal products. This 120,000-square-foot plant near Arras (Pas-de-Calais) will be producing 10% immunoglobulins, fibrinogen and albumin – all medicinal products that are increasingly in demand in France and worldwide.

The new facility is designed principally to optimize production costs and respond to the highest global standards; it will therefore enable LFB to supply the whole world with products made in France. The new industrial site in Arras is progressing: infrastructure is complete and equipment is becoming operational. The site has already started production of water for injections which is an essential prerequisite for the qualification phase.

As part of the commissioning of clean utility production equipment, LFB has chosen to outsource the periodic metrology of all water manufacturing equipment for pharmaceutical use. LFB entrusts the service provider with metrology, the objective of which is to take charge of all the

periodic metrological checks of the equipment below. The services to be implemented must guarantee LFB compliance with its obligations as owner as defined by the regulations in force, standards and rules of the art.



Solution

Non-intrusive ultrasonic technology from Flexim has always been the best choice when it comes to the highest hygiene requirements. Because measuring from the outside of the pipe not only means measuring from the safe side, it also guarantees absolute purity and hygiene. For this reason, several stationary FLUXUS® F721 ultrasonic systems as well as older FLUXUS® F704 are used at LFB, mainly for flow measurement of raw materials for production.

A key raw material is Water for Injection (WFI), which is prepared from municipal drinking water in a state-of-the-art facility through softening, filtration, and finally distillation. Permanently installed FLUXUS® flowmeters monitor the valuable utility in 14 production units. So what could be more obvious than entrusting the monitoring and predictive maintenance to the manufacturer?

For the measurement experts from the Flexim France team, setting up and evaluating flow measuring points with clamp-on ultrasonic technology is routine.

In addition, they have powerful tools: The acoustic measurement technology provides meaningful diagnostic values that can be transmitted, visualized and evaluated with FluxData or as part of the Advanced Meter Verification and which allow a reliable evaluation of the measurement quality.

However, the most important tool of every Flexim employee in the field is their portable flow meter. A temporary flow measuring point can be set up in next to no time with the FLUXUS® F601. For the calibration, the clamp-on ultrasonic transducers of the FLUXUS® F601 are attached as a test standard in series with those of the flow meter permanently installed in the skid and the measured values are compared with each other. The deviations between the measured values of the device under test (data from the process control system) and the test standard (data from FluxDiag) must remain within the narrow tolerance range specified by LFB. The calibration is recorded in detail in a protocol and a calibration certificate is then issued. Of course, the portable flowmeters used by Flexim as test standards are also subject to regular metrological checks and calibrations according to COFRAC.



The new LFB plant at Arras

© LFB



Water for Injection (WFI) is an essential raw material for the manufacture of medicines.



The calibration is carried out by comparing the measured values of the flow meter permanently installed in the skid with those of the test device temporarily attached in series.

LABORATOIRE FLEXIM

d. Certificat étalonnage du débitmètre Fixe :

Certificat de calibration
SKID PC-23

Certificate No. F 704TE-70427060_14.09.2022

Appareil Etalonné (A.E)
Transmetteur: F 704 No. Série 70427060

EMT: 10,0000 %

Résultats du test

A.E		ETALON		RESULTAT	
DEBIT CORR	DEBIT mesuré	DEBIT de référence	Erreur Relative	Test ok	
m³/h	m³/h	m³/h	%	VALIDE / NON VALIDE	
11,00	10,970	10,740	2,1881	VALIDE	

L'instrument indiqué répond à la précision du débit mesuré par rapport à un instrument étalonné (Validé/Non Validé).

L'instrument (A.E) spécifié ci-dessus a été vérifié par un instrument calibré.

Type: Fabricant: Type: Calibré le: Certificat No:

VALIDE

The calibration is precisely recorded and confirmed with a certificate.



The test is also documented on the transmitter.

Measuring Points and Instrumentation

Pipelines	typically stainless steel, diameter ~ 2" – 6"
Medium	ultra-pure water
Measuring system	2 stationary FLUXUS® G721 ultrasonic measuring systems for gases
	1 portable FLUXUS® F601 with two pairs of CDQ and CDP clamp-on ultrasonic transducers as well as transducer mounting system fastening shoes

Advantages

- On-site non-intrusive calibration of flow meters without any disruption to production
- Extremely versatile measuring system: a single measuring device for a large number of measuring points and measuring tasks
- Fast and competent service by the Flexim France team
- Flexim has been entrusted with this task since the permanently installed flow meters were commissioned

Customer

LFB, Arras Plant, Bailleul Sir Berthoult, Departement of Pas-de-Calais, France

LFB (Laboratoire français du Fractionnement et des Biotechnologies) is a biopharmaceutical group that develops, manufactures and markets plasma-derived or recombinant therapeutic proteins for the treatment of serious and often rare diseases in several important therapeutic areas, including hematology, immunology and emergency medicine. LFB is the leading manufacturer of plasma-derived medicines in France and number 7 in the world. LFB currently sells 15 products in around 40 countries and achieved sales of EUR 458.8 million in 2021. The group employs more than 2,500 people, including more than 2,000 in France.



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