

CPSL Language Services: The importance of accurate Batch Manufacturing Records (BMRs).

When nothing can afford to go wrong!

Accurate and compliant translations that are delivered on time means successful FDA and EMA submission and approval processes.

BMRs	CHALLENGES	SOLUTIONS Professional Linguistic Guidance & Translation Services	HOW WE DO IT CPSL Workflow
 Regulatory Compliance	Navigating complex regulations and ensuring adherence. A BMR is a written document that outlines the entire drug manufacturing process. It is mandated by regulatory bodies such as the FDA, the EMA, and other health authorities around the world. Accurate BMRs are crucial for passing regulatory audits and inspections.	Support for Global Compliance Expert guidance helps you maintain compliance with local and international regulations across multiple regions and ultimately ensures support for global market access.	After the project files are received, a kickoff meeting is held between the client and a BMR expert from our technical team to define the workflow and the schedule.
			Preparation of any handwritten or manual records.
			Creation and use of Word templates, if needed, to optimise delivery times.
 Product Quality	Consistency & Traceability Maintaining translation accuracy and the consistent use of terminology, including expertise in technical language. BMRs often contain technical language that must be precise and clear. Our experienced specialists understand the complex terminology and regulatory requirements.	Expert translators with in-depth knowledge of the industry .	QA of prepared files before the translation phase. Validation phase: any doubt is resolved in this phase, given that handwritten text is sometimes not legible. Post-translation DTP: knowledge of FDA and EMA guidelines Cover page and index creation, if needed.
		Centralised glossary management systems to maintain terminological consistency across all documents and languages.	
		Computer-Assisted Translation tools that are updated in real time.	
		QA processes that use the latest technology to ensure accuracy .	
		Detailed checklists for translators, project managers, and DTP personnel to guarantee that every document adheres to requirements.	
		Comprehensive documentation and audit trails for all translation projects to ensure traceability and accountability .	
 Layout	The nature of the work itself is a complex process that requires precision and multiple levels of QA. Good DTP is crucial in this process. An experienced provider with a systematic and flawless workflow is essential.	Ensure formatting consistency across multiple languages.	Validation of the final layout after translation, with cover page and index validation, if needed.
		Templates that comply with FDA guidelines.	Implementation of feedback: analyse any corrections sent by the client to determine if terms need to be added to glossaries.
		Templates that comply with FDA and EMA guidelines.	PDF compilation according to FDA & EMA guidelines.
 Compilation	Adhering to FDA-specific and EMA-specific formats and guidelines.	Guarantees that documents are complete and accurate.	 Ensure Compliance and Quality with expert BMR/BPR Translation Partner up with a professional language services provider to meet global regulatory standards, maintain product consistency, ensure operational efficiency, and achieve seamless market access.
		Compliance checklists.	
 Time Management	Avoiding delays in product approval.	Experienced project managers who oversee timelines, coordinate teams, monitor workflows, and ensure that project deadlines are met.	
		Efficient project management with clear communication channels and transparency.	
		Back-up translators and Project Managers.	
		Translation Memories that help reduce turnaround times.	
 Data Integrity	Protecting sensitive information throughout the process. BMRs must be accurate and error-free to maintain data integrity.	ISO 27100 certification which includes communication channels and confidentiality.	