MaFel Core
Smart Lab Management Platform

REGULATION · COMPUTERIZED SYSTEMS · DATA INTEGRITY

Same Region, Four Different Floors: Computerized Systems Compliance Across Mercosur

Data integrity and computerized-systems rules in pharmaceutical quality control are converging on the same principles across South America — and diverging sharply on how, when, and whether they're enforced.

Álvaro Codas · MaFel Core · August 2026

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Independent regulatory analysis. Citations and jurisdictional limitations are described in the text.

IN BRIEF. Across Mercosur, the principles governing computerized systems are converging, while their legal status and enforcement remain country-specific. Paraguay, Argentina, Brazil, and Uruguay currently represent four distinct regulatory floors.

Ask a quality manager running a QC laboratory in Asunción, Buenos Aires, São Paulo, or Montevideo whether their computerized systems need to be validated the way EU Annex 11 or PIC/S PE 009 describe, and you'll get four different, equally correct answers. Not because the underlying principles differ — attributable, legible, contemporaneous, original, accurate data is the same idea everywhere — but because each country wrote that requirement into law on a different page, at a different time, with a different door left open or closed behind it.

For a region that increasingly sells across its own borders, that patchwork is not a footnote. It's the actual compliance map.

1 Paraguay just wrote the strictest rule in the bloc — and made it self-updating

On 7 May 2026, Paraguay's health authority, DINAVISA, adopted the full PIC/S PE 009-17 guide — Parts I and II and a named list of annexes, including Annex 11 (Computerised Systems) and Annex 15 (Qualification and Validation) — as binding technical law, through Resolución DINAVISA N° 183. There was no adaptation period: Article 10 makes it effective on the date of signature.

The clause that matters most for anyone building or buying software for a Paraguayan lab is Article 2's wording: the guide applies "in its current versions and updates." When PIC/S finalizes the Annex 11 revision currently in public consultation, it becomes Paraguayan law automatically — no new resolution required.

Paraguay had already laid the groundwork two years earlier. Resolución DINAVISA DG N° 197/21's Appendix 5 ("Sistemas Informáticos") — the country's de facto Annex 11 — explicitly incorporates GAMP 5 (ISPE) by reference: "...guías GAMP versión 5 (ISPE) — A Risk-based Approach to Compliant GxP Computerized Systems — u otras actualizadas con requerimientos similares o superiores." That's a direct citation, confirmed against the primary text, not a secondary-source paraphrase.

Paraguay is not, however, a PIC/S member. It adopted the guide unilaterally.

2 Argentina built comparable walls, in different bricks — and one brick is still unverified

ANMAT's core GMP framework was rewritten in June 2023 (Disposición 4159/2023, repealing the 2018 rule), and its preamble cites alignment with WHO, PIC/S PE 009-16, ICH, and ISO. The current guide includes an Annex 6, "Sistemas Informáticos" — Argentina's structural equivalent to Annex 11.

Here's where honesty about sourcing matters: several consultancy blogs claim Annex 6 names GAMP 5 explicitly, the way Paraguay's Appendix 5 does. That claim traces back to commentary on the previous (2018) version of the annex, not to a verified read of the current 2023 text — official government mirrors blocked automated retrieval during this research, and no ANMAT text I could independently confirm uses the term "ALCOA" or "ALCOA+" either. Treat the GAMP 5 citation as plausible, not confirmed, until someone reads the current annex directly.

What is confirmed: Argentina joined PIC/S in January 2008 — the earliest accession in the region by over a decade — and a separate 2025 disposition (7998/2025) streamlines recognition of GMP certificates for manufacturing plants from PIC/S or Mercosur countries. It says nothing specific about QC laboratories as a category.

3 Brazil skipped the annex format entirely and wrote a standalone law

ANVISA didn't bolt a computerized-systems annex onto its general GMP resolution (RDC 658/2022). It issued a separate, dedicated instrument — Instrução Normativa 134/2022, "Boas Práticas de Fabricação complementares aos sistemas computadorizados" — plus a implementation guide, Guia 33/2020. IN 134/2022 formally repealed its 2019 predecessor.

Brazil became PIC/S's 54th participating authority on 1 January 2021. But membership didn't produce mutual recognition: ANVISA's own published FAQ states plainly that no mutual recognition of GMP certificates exists, even between Mercosur partners — on-site inspection remains the default, with document-based reliance available only as a narrowing exception under newer instruments (IN 292/2024, IN 451/2026). PIC/S membership, in other words, buys credibility, not a shortcut.

As in Argentina's case, claims that Guia 33/2020 names GAMP 5 or ALCOA+ explicitly come from consultancy sources, not a verified primary-text read.

4 Uruguay hasn't written this rule yet — and that's the most interesting data point

This is the gap worth naming out loud: no Uruguayan regulation requiring computerized-systems validation or ALCOA-type data-integrity principles for pharmaceutical QC surfaced anywhere in this research — not a decree, not a guide, not a resolution. Uruguay has, until now, been the only country in the region without an independent medicines regulator at all; a October 2025 law creates one (AViSU, the Agencia de Vigilancia Sanitaria del Uruguay), still in the process of standing up as of this writing. Uruguay is not a PIC/S member and has no resolution adopting PE 009.

That's not a criticism of Uruguayan regulators — building a regulator from scratch is a multi-year undertaking. It's a data point for anyone assuming "Mercosur" implies a shared floor. It doesn't, yet.

5 PIC/S membership and PIC/S alignment are not the same door

It's worth being precise about a distinction that gets collapsed constantly in industry conversation: adopting PIC/S guidance and being a PIC/S member are different things, done by different actors, for different reasons. Argentina (2008) and Brazil (2021) are full members, subject to PIC/S's own peer-assessment process. Paraguay adopted the PE 009 guide by unilateral resolution without seeking membership. Uruguay has done neither. Mexico, outside this region's Mercosur core, has been a member since 2018.

For a laboratory or a software vendor, the practical consequence is this: which country's inspectors will accept which country's evidence depends on membership status, not just on whether the underlying guidance texts happen to match.

6 What actually has to be true, regardless of which door you're standing behind

Strip away the differences in legal architecture — annex versus standalone instrument, member versus unilateral adopter, self-updating clause versus static text — and the four frameworks converge on the same operational demands for any system handling regulated data:

Every user needs an individual account, not a shared login. The system — not a person — must generate the audit trail, and that trail has to capture why a value changed, not just that it did. Someone has to actually review that trail on a defined schedule; having it exist isn't the same as anyone reading it. Manual entry of critical data needs a second check. Backups need to have been tested by an actual restoration, not assumed to work. And if the vendor disappears or the system goes down, there has to be a documented fallback that keeps the lab running.

None of that is exotic. It's also, in practice, the part almost no lab actually does well — the regulatory text in every one of these four countries treats "having a record" and "regularly reviewing that record" as separate, both-mandatory requirements, and the second one is where audits find the gaps.

7 The uncomfortable part for anyone selling software regionally

A system built to satisfy Paraguay's self-updating PIC/S adoption, Argentina's Annex 6, Brazil's IN 134/2022, and whatever Uruguay's incoming AViSU eventually writes is not four compliance projects. It's one architecture with four evidence packages layered on top — which is a very different, and much cheaper, thing to build, provided someone maps the four floors correctly before writing a line of code.

Getting that map wrong in either direction carries a cost: overbuilding for a jurisdiction with a lighter regulatory floor wastes budget a small lab doesn't have; underbuilding for one with a stricter, self-updating floor — Paraguay, at the moment — creates a gap an inspector will eventually find.

The author develops software for laboratories operating in regulated environments across the region. This article does not analyze or endorse any particular product, and its regulatory citations were checked against primary government sources wherever those sources were publicly accessible; where a claim could only be traced to a secondary source, that is stated explicitly above.

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