Risk Assessment and Regulatory Response to Systematic Pharmaceutical Quality Failures: Lessons from Argentina's Contaminated Fentanyl and Dexamethasone Crisis

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ABSTRACT

The pharmaceutical industry operates under strict regulatory frameworks ensuring medicine safety, quality, and efficacy. In Argentina, the National Administration of Medicines, Food and Medical Technology (ANMAT) and other local jurisdictions oversee regulatory compliance through Good Manufacturing Practices (GMP) and quality control standards. Despite widespread industry commitment to patient safety, systematic failures by certain manufacturers can cause an unprecedented outbreak and major health crises. To examine quality incidents involving the products of a specific Marketing Authorization Holder (MAH) and its co-contracted manufacturing site between 2018 and 2025, to assess GMP and quality control deficiencies, regulatory responses, and legal responsibilities under Argentine Law 16.463 and provincial regulations culminating in a major pharmaceutical adulteration crisis in South America.

Keywords: pharmacovigilance, pharmaceutical adulteration, regulatory affairs, fentanyl.

I. Introduction

The pharmaceutical industry serves as a fundamental pillar of public health, providing essential medicines for conditions ranging from common ailments to complex diseases. The sector operates under strict regulatory frameworks designed to guarantee product safety, quality, and efficacy. In Argentina, the National Administration of Medicines, Food and Medical Technology (ANMAT) serves as the federal regulatory authority overseeing compliance with these standards, including Good Manufacturing Practices (GMP) and quality control regulations (ANMAT, 2017).While most pharmaceutical companies maintain ethical standards to patient safety, a few exceptions exist where actors engage in behaviors prioritizing commercial interests over patient welfare. Recent incidents involving a MAH's products have exposed critical failures that contrast starkly with industry standards, resulting in massive product recalls,

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marketing bans, and devastating patient health impacts, including deaths associated with contaminated drugs (ANMAT, 2025c). This case study offers critical insights into pharmaceutical regulatory framework vulnerabilities and proposes evidence-based recommendations for strengthening oversight within regulatory science.

II. Methods

Study Design and Data Sources

A comprehensive analysis of pharmaceutical quality incidents involving the MAH was conducted covering the period 2018-2025. The methodology employed systematic data collection from multiple sources using thematic analysis to identify patterns of regulatory non-compliance and their public health consequences. The data collected included ANMAT and Buenos Aires provincial alerts, scientific publications, and media reports to document microbial contamination incidents, labeling errors, and traceability deficiencies by the MAH and contractor. Two paradigmatic cases were analyzed in detail -the 2023 dexamethasone outbreak in Concordia and the 2025 fentanyl contamination crisis- and evaluated their public health impact and regulatory oversight implications.

Primary Data Sources included the following:

- Official documents, inspection and alerts from ANMAT's website
- Province of Buenos Aires Ministry of Health communications
- ANMAT alerts, dispositions, resolutions, and press releases concerning the MAH and contracted manufacturing site.

Secondary Data Sources included the following:

- Systematic review of media reports from reputable Argentine news outlets
- Peer-reviewed scientific publications documenting outbreaks linked to company products
- Judicial proceedings documentation and court records

Data Collection and Analysis

Keyword searches were performed across ANMAT archives and media databases using Spanish terms: the name of the MAH and its contracted manufacturing site, "fentanyl contamination," "dexamethasone outbreak," "ANMAT recalls," and "pharmaceutical quality failures in Argentina."

To synthesize collected data, a thematic analysis was applied and identified:

- Recurring regulatory non-compliance patterns
- Specific quality control deficiencies
- Timeline and nature of ANMAT regulatory interventions
- Public health impacts

The information was triangulated across sources to corroborate findings, build timelines, and strengthen validity.

III. Results

Overview of Quality Incidents (2018-2025)

Data from ANMAT alerts revealed systematic incidents associated with the MAH products spanning 2018-2025 (Ministry of Health of the Argentine Nation, 2025). These incidents reflect systematic problems in manufacture, control, and distribution, including microbial contamination, labeling errors, traceability deficiencies, unauthorized packaging, suspended particles in injectable solutions,

and quality test failures. Records from Buenos Aires Province Ministry of Health indicate that no alerts were issued prior to the fentanyl crisis for either the MAH, or the contracted manufacturing site, despite sixteen documented federal violations, (See Appendix - Table 1).

Affected products encompassed medications used in hospitals and critical settings. Notable incidents included diclofenac and morphine 1% batches recalled due to labeling errors, where morphine-labeled secondary packaging contained diclofenac ampoules—potentially fatal in clinical settings (ANMAT, 2025d). Parenteral solutions including Sodium Chloride and 5% Dextrose were recalled due to packaging irregularities, particle presence, and microbial growth (ANMAT, 2025a, 2025b), as shown in Appendix - Table 1. Additionally, the investigation identified two particularly significant cases that exemplify the scope and severity of these failures. Overall, the MAH and its contracted site demonstrated multiple GMP non-compliance/observations in different instances, see Appendix - Table 2. No specific details about the nature of the findings were available.

IV. Case Study 1: The 2023 Dexamethasone Outbreak in Concordia

A hospital outbreak of Ralstonia mannitolilytica infections was traced to contaminated dexamethasone ampoules produced by the MAH, affecting six immunocompromised female patients undergoing chemotherapy at an 80-bed tertiary institution in Concordia, Entre Ríos, in August 2023 (Prieto et al., 2024). All six patients subsequently developed catheter-related bloodstream infections. Epidemiological and bacteriological analyses traced contamination to specific 2 ml dexamethasone ampoule batches positive for Ralstonia mannitolilytica, which can survive in low-nutrient environments and contaminating pharmaceuticals. Despite a doctor's August 2023 report to ANMAT submitted via the pharmacist's college and supported by internal investigations confirming contamination, ANMAT's October 20, 2023, response stated the product met approved specifications, effectively dismissing the concerns (Hartmann, 2025).

V. Case Study 2: The 2025 Fentanyl Contamination Crisis

The most alarming case involved the MAH's fentanyl, a hospital-use opioid analgesic. Contaminated batches with Klebsiella pneumoniae and Ralstonia pickettii were linked to 105 reports: 62 confirmed exposure cases and 5 suspected cases, with 50 deaths across six Argentine jurisdictions (Ministry of Health of the Argentine Nation, 2025; ANMAT, 2025e). The ages of the reported patients ranged from 0 to 96 years, with a median of 57 years. The fatal outcome occurred with a median of 12 days between administration and death. This incident triggered regulatory actions by ANMAT and judicial investigations leading to asset freezes, travel bans, and arrests of individuals associated with the company (Klipphan, 2025a).

VI. Judicial Evidence of Systematic Deception

Recent judicial proceedings revealed systematic negligence through internal communications recovered during investigation. Judge interrogations and cellphone analysis of ten defendants,

including the company owners, uncovered damning evidence of deliberate misconduct. Internal messages between employees and management revealed systematic deception and quality control manipulation. Particularly alarming communications showed employees discussing the need to "lie" in reports when lacking proper testing materials. Quality Control Supervisor asked "What do I do? Do I lie in the reports?" with Quality Control Chief responding "Good morning, … It seems we have no choice but to lie" (Klipphan, 2025c).

Evidence documented deplorable facility conditions including loose roof sheets, pigeons in storage areas, spiders in production areas, collapsed walls, electrical system failures days before the fatal fentanyl batch production, and missing records for critical manufacturing processes, etc. Communications from December 2024 to April 2025 describe what prosecutors characterized as "deliberate conduct of serious non-compliance with current regulations, systematic and repeated, a completely corrupted organizational culture" directly contributing to patient deaths (Klipphan, 2025c).

VII. Discussion

The systematic failures identified in this investigation reveal a complex interplay of regulatory, manufacturing, and oversight deficiencies that culminated in preventable patient harm. The contaminated pharmaceutical incidents examined represent more than isolated quality control lapses—they demonstrate fundamental breakdowns of this specific MAH quality assurance system.

Regulatory Framework Violations and Manufacturing Quality Failures:

The GMP violations identified at the contracted manufacturing site represent a cascade of interconnected failures across multiple critical control points. The absence of microbiological controls in intermediate and final production stages shows how manipulated quality control data circumvents oversight and allow contaminated products to reach vulnerable patients (ANMAT, 2024, 2025i; Klipphan, 2025c).

The presence of water-associated organisms such as Ralstonia and Klebsiella in contaminated products indicates fundamental deficiencies in water system qualification and environmental monitoring protocols. Such contamination patterns are consistent with inadequate sterilization parameters, compromised filtration systems, and defective media-fill validation procedures.

The clinical implications of these failures are immediate and severe, particularly for immunocompromised patients and neonates, who face heightened risks of sepsis, catheter-related bloodstream infections, and mortality (Ministry of Health of the Argentine Nation, 2025).

Beyond microbiological concerns, the identification of particulate contamination, including black particles and metal fragments, reflects broader maintenance and cleaning validation failures that compromise product integrity across multiple dosage forms. Particulates pose risks such as vascular embolization, phlebitis, and inflammatory reactions in parenteral products, their presence in oral formulations suggests line-clearance failures and inadequate in-process controls.

Legal Compliance and Regulatory Authority Response:

The violations documented in this investigation represent clear contraventions of Law 16.463 and Buenos Aires Provincial Laws 11.405 and 10.606, which establish comprehensive frameworks requiring pharmaceutical products to demonstrate efficacy, safety, and quality throughout the supply chain (Argentina, 1964; Buenos Aires Province, 1987, 1993). Internal communications indicating deliberate regulatory circumvention suggest potential criminal conduct.

ANMAT's regulatory response demonstrated commitment to patient safety through proactive crisis management, including the issuance of specific product alerts and the suspension of manufacturing activities via Disposition No. 3158/25 following inspection findings (ANMAT, 2025f). However, the temporal sequence of events raises critical questions about the effectiveness of current inspection and enforcement mechanisms. Contaminated fentanyl was manufactured on December 18, 2024—six days after the conclusion of inspection #2024/3332-INAME-677— and fatality reports began on April 15, 2025 (See Appendix – Table 2. This timeline suggests that current frameworks may not prevent defective product release during periods of scrutiny.

Public Health Impact and Risk Management Implications:

The public health consequences extended beyond immediate harm, threatening supply-chain integrity and public confidence in oversight. The contaminated fentanyl incident resulted in 105 reported cases (62 confirmed and 5 suspicious), including 50 deaths, highlights the disproportionate impact on high-risk patient groups (Ministry of Health of the Argentine Nation, 2025). Similarly, the 2023 dexamethasone contamination affected six breast cancer patients, requiring invasive interventions and demonstrating how quality failures can compound the challenges faced by patients with serious underlying conditions (Prieto et al., 2024).

From a risk management perspective, these incidents underscore the critical importance of robust hazard identification, risk assessment, and mitigation strategies throughout pharmaceutical manufacturing operations. Systematic falsification of quality-control records allowed contaminated products to enter supply chains without safety assessment, reflecting a breakdown of risk management.

The economic implications extend beyond immediate healthcare costs to encompass loss of public confidence, potential legal liabilities, and broader effects on Argentina's pharmaceutical market competitiveness. These broader impacts underscore the need for comprehensive reforms that address not only technical compliance issues but also the underlying systemic factors that enabled such widespread quality failures.

Systemic Drivers and Quality Management System Failures:

The pattern of violations identified across multiple product lines and manufacturing processes indicates fundamental failures in the quality management system at the contracted manufacturing site, compounded by insufficient oversight by the marketing authorization holder. The inadequacy of quality risk management protocols allowed high-risk manufacturing changes and

deviations to proceed without formal assessment or appropriate mitigation measures. This violates established pharmaceutical quality principles requiring systematic evaluation of all changes that could impact product quality, safety, or efficacy.

The deficiencies in microbiological control strategies across water systems, cleanroom operations, and aseptic processing represent particularly critical failures given the life-threatening nature of microbial contamination in sterile products. Incomplete process validation protocols, including inadequate media-fill studies and filter integrity testing, created conditions where contaminated products could be released without detection.

The absence of effective traceability systems for controlled and high-critical medicines further compromised the ability to implement rapid containment measures and conduct effective pharmacovigilance activities. This is particularly concerning for products such as fentanyl, where traceability gaps can enable diversion and obstruct efforts to protect public health during contamination events.

VIII. Recommendations

Based on these incidents analysis, key recommendations emerge for strengthening pharmaceutical regulation in Argentina:

Immediate Regulatory Actions

- Implement mandatory unit traceability for high-criticality drugs including controlled substances.
- Implement unannounced inspections for all sterile injectable manufacturers at least annually preventing advanced regulatory visit notification.
- Develop rapid response protocols for contamination reports including immediate investigation and public communication.
- Mandate manufacturing license suspension for first contamination offense and for companies violating suspension orders or demonstrating recidivist behavior.

Systemic Regulatory Reforms

- Strengthen the legal frameworks distinguishing technical director responsibility from management decisions overriding safety protocols.
- Implement whistleblower protection mechanisms for industry employees reporting safety violations.
- Establish mandatory continuing education programs for pharmaceutical professionals on ethical responsibilities and patient safety.
- Create inter-agency coordination mechanisms ensuring consistent regulatory oversight across jurisdictions.

Quality Assurance Enhancement

- Require robust internal audit systems with external validation.
- Mandate real-time quality deviation reporting to regulatory authorities.
- Establish international cooperation frameworks for sharing problem manufacturer information.
- Develop advanced analytical capabilities for detecting pharmaceutical contamination and adulteration.

Implications for Regulatory Science

These cases offer regulatory-science insights: frameworks must detect and prevent systematic deception while maintaining efficiency for compliant

manufacturers. The case highlights needs for regulatory approaches beyond traditional inspection and testing to include behavioral analysis and organizational culture assessment.

Internal communications and organizational culture roles in regulatory compliance represent emerging regulatory science areas deserving further investigation. Understanding how organizational pressures lead to systematic safety violations may inform more effective regulatory intervention development.

This case underscores pharmaceutical regulation international cooperation importance, as regulatory system problems in one country can have global pharmaceutical safety and public health implications.

IX. Conclusions

These incidents serve as critical reminders of GMP and quality control importance in pharmaceutical industry (World Health Organization, 2020). Systematic violation nature, revealed through internal communications showing employees acknowledging they had "no choice but to lie" in quality reports, demonstrates complete ethical and professional standards breakdown resulting in 105 reported cases with 50 suspected deaths.

Judicial evidence exposes what prosecutors describe as a “completely corrupted organizational culture” that prioritizes commercial interests over patient lives. Modifying the framework of shared responsibility between companies and technical directors—as established by Law 16.463 (Argentina, 1964) and Buenos Aires Province Laws 11.405 and 10.606—is critical. The current framework prevents technical directors from reporting company violations without incriminating themselves. Additionally, regulatory suspensions must be effective immediately upon issuance, without administrative delays that allow continued operations during appeals processes.

However, distinguishing between general pharmaceutical industry conduct—characterized by quality and safety dedication—and actions of certain actors is essential. While ANMAT acted resolutely responding to this crisis, structural challenges including lack of traceability for certain drugs, inadequate inspection protocols, and insufficient regulatory violation penalties must be urgently addressed to prevent similar tragedies.

This case underscores critical needs for constant vigilance and close collaboration between regulators, manufacturers, and healthcare professionals ensuring medicine integrity. The pharmaceutical industry has ethical and legal duties to prioritize patient safety. These incidents should prompt stronger quality and oversight systems at all levels to prevent actors from compromising public health through deception and regulatory evasion.

Lessons from this crisis must inform global regulatory science, emphasizing frameworks that identify and prevent organizational cultures that systematically violate safety standards while supporting companies committed to patient welfare.

IX. Conflict of Interest

The author declares no financial or other substantive conflict of interest that might be construed to influence the results or interpretation of this work. No sources of

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Appendix I: ANMAT Alerts and Recalls for the MAH Products (2018-2025)

Year	Affected product/drug	ANMAT Alert – Recall
2018	Lidocaine hydrochloride 10 mg/ml, 1% - contracted manufacturing company product	Low concentration of the active ingredient
2018	Metamizole (dipyrone) 2.5 g/5 ml - contracted manufacturing company product	Presence of particles
2023	Metformin hydrochloride 850 mg - MAH	Metal fragment found inside a blister cavity
2023	Diclofenac sodium 25 mg/ml - MAH	Black particles in suspension
2023	Paracetamol 500 mg - MAH	Out-of-specification results for hardness and friability tests, with broken tablets found inside blister cavities
2023	Sodium chloride 0.9 g/100 ml - MAH	Black particles in suspension
2024	Ciprofloxacin 200 mg/100 ml -MAH	Particles and visible microbial contamination

2024	Dexamethasone phosphate 4 -mg/ml MAH	Product packaged in a container not authorized by the Health Authority
2024	Diclofenac sodium 25 mg/ml -MAH	Secondary packaging labeled “morphine 1%” found to contain ampoules of the product diclofenac MAH
2025	Morphine hydrochloride -trihydrate 10 mg/ml - MAH	Secondary packaging labeled “morphine 1%” found to contain ampoules of the product diclofenac MAH
2025	Propofol 10 mg/ml - MAH	Product lacks traceability labeling Not registered in the Registry of Medicinal Specialties. The certificate number is registered under the ownership of another company. Therefore, the product was illegitimate
2025	Dopamine hydrochloride 40 mg/ml - MAH	Product lacks traceability labeling Not registered in the Registry of Medicinal Specialties. The certificate number is registered under the ownership of another company Therefore, the product was illegitimate
2025	Dopamine hydrochloride 20 mg/ml - MAH	Product lacks traceability labeling Not registered in the Registry of Medicinal Specialties. The certificate number is registered under the ownership of another company. Therefore, the product was illegitimate
2025	Fentanyl (citrate) 0.05 mg/ml - MAH	Suspected microbial contamination in ampoules of the product

2025	Calcium gluconate100 mg/ml - MAH	Metal fragments were found inside a blister cavity
2025	Ringer's lactate solution - MAH	Visible microbial contamination and the batch was packaged in containers with an open system, thus not complying with ANMAT Regulation No 11857/17

Source: ANMAT Alerts, 2025g, 2025h

Table 2: ANMAT Inspections to the MAH and contracted manufacturing site (2018-2025)

Company	Year	Type of inspection	Inspection #	Result
Contracted site	2018	Unplanned	2018/1377-INAME-167	No significant observations.
Contracted site	2018	Unplanned	2018/1378-INAME-168	Significant observations.
Contracted site	2018	Unplanned	2018/1379-INAME-169	Significant observations.
Contracted site	2018	Unplanned	2018/1380-INAME-170	No significant observations.
Contracted site	2018	Unplanned	2018/1381-INAME-171	No significant observations.
Contracted site	2018	GMP, planned	2018/1381-INAME-191	Significant observations.

MAH	2018	Unplanned	2018/3422-INAME-425	Significant observations.
Contracted site	2018	Unplanned	2018/3774-INAME-477	No significant observations.
MAH	2019	GMP, Unplanned	2019/1274-INAME-173	Significant observations.
MAH	2015	Unplanned	2018/3884-INAME-487	Significant observations.
MAH	2020	GMP, Unplanned	2020/442-INAME-92	No observations.
MAH	2023	Unplanned	2022/2047-INAME-491	Closed plant due to holidays
MAH	2023	Unplanned, recall	2023/466-INAME-93	No significant observations.
Contracted site	2022	Unplanned	2022/85-INAME-23	Significant observations
Contracted site	2022	Planned, plant modification	2022/221-INAME-57	No significant observations.
Contracted site	2022	GMP, Unplanned	2022/222-INAME-58	Significant observations.
Contracted site	2022	Unplanned	2022/1912-INAME-457	No significant observations.

Contracted site	2024	GMP	2024/3332-INAME-677	Significant observations.

Fuente: ANMAT, 2025i