

UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
REGION IX



In the matter of:	)	U.S. EPA Docket No.
	)	
	)	RCRA-09-2024-0099
	)	
Edwards Lifesciences, LLC	)	<b>CONSENT AGREEMENT AND</b>
CAR000011122	)	<b>FINAL ORDER PURSUANT TO</b>
	)	<b>40 C.F.R. SECTIONS 22.13 AND 22.18</b>
	)	
Respondent.	)	
_____	)	

**CONSENT AGREEMENT**

**A. PRELIMINARY STATEMENT**

1. This is a civil administrative enforcement action instituted pursuant to Section 3008(a)(1) of the Resource Conservation and Recovery Act (“RCRA”), as amended, 42 U.S.C. § 6928(a)(1), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits, as codified at 40 Code of Federal Regulations (“C.F.R.”) Part 22 (“Consolidated Rules”).
2. The Administrator of the United States Environmental Protection Agency (“EPA”) has delegated enforcement authority under Section 3008 of RCRA, 42 U.S.C. § 6928, to the EPA Regional Administrators, with delegation 8-9-A, last revised February 4, 2016. The Regional Administrator, EPA Region IX, in turn, re delegated that authority to the Director of the Enforcement Division (now the Enforcement and Compliance Assurance Division), Region IX, with delegation R9-1200 TN 111, dated January 22, 2016, hereinafter, “Complainant”.
3. Respondent is Edwards Lifesciences, LLC (“Respondent” or “Edwards”).
4. This Consent Agreement and Final Order (“CA/FO”), pursuant to 40 C.F.R. §§ 22.13 and 22.18, simultaneously commences and concludes this proceeding, wherein EPA alleges that Respondent violated requirements of Subtitle C of RCRA, 42 U.S.C. § 6921 *et seq.*, and state regulations adopted pursuant to the State of California’s (“State’s”) authorized hazardous waste management program under RCRA.
5. The Parties agree that settling this action without the filing of a complaint or the adjudication of any issue of fact or law is in their respective interests and in the public interest.

## **B. STATUTORY AND REGULATORY FRAMEWORK**

6. Subtitle C of RCRA requires the EPA Administrator to promulgate regulations establishing a hazardous waste management program. Section 3006 of RCRA, 42 U.S.C. § 6926, provides, *inter alia*, that authorized state hazardous waste management programs are carried out under Subtitle C of RCRA. Therefore, a violation of any requirement of law under an authorized state hazardous waste program is a violation of a requirement of Subtitle C of RCRA.
7. The State of California (“State”) received authorization to administer the hazardous waste management program in lieu of the federal program pursuant to Section 3006 of RCRA, 42 U.S.C. § 6926, and 40 C.F.R. Part 271, on or about August 1, 1992. This authorization was updated on September 26, 2001, (*see* 66 FR 49118, September 26, 2001), on October 7, 2011, (*see* 76 FR 62303, October 7, 2011), and again on January 14, 2020 (*see* 85 FR 2038, as corrected [*see* 86 FR 29207, June 1, 2021]). The authorized hazardous waste program is established pursuant to the Hazardous Waste Control Law, Chapter 6.5 of Division 20 of the California Health and Safety Code, and the regulations promulgated thereunder at Title 22, Division 4.5 of the California Code of Regulations, 22 C.C.R. §§ 66001 *et seq.* The State is authorized for all the hazardous waste management regulations referenced in this CA/FO.<sup>1</sup>
8. A violation of the State’s authorized hazardous waste program, found at Health & Safety Code § 25100 *et seq.*, constitutes a violation of Subtitle C of RCRA and, therefore, a person who violates California’s authorized hazardous waste program is subject to the powers vested in the EPA Administrator by Section 3008 of RCRA, 42 U.S.C. § 6928.

## **C. GENERAL ALLEGATIONS**

9. Respondent is a medical device manufacturing company that owns and operates a manufacturing facility, located at 17221 Red Hill Avenue, Irvine, California, with an EPA ID number of CAR000011122 (the “Facility”).
10. Respondent manufactures medical devices at the Facility. Various solutions are made and used in the manufacturing process, including a sterilant solution. The spent sterilant solution is considered RCRA ignitable waste with a RCRA code of D001. That waste is

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<sup>1</sup> All citations to the “C.C.R.” refer to Division 4.5 of Title 22 of the current California Code of Regulations. EPA is enforcing California hazardous waste management program requirements as approved and authorized by the United States. As a convenience, corresponding Federal citations are provided in brackets.

stored in the Waste Storage Tank, which is comprised of two cylindrical tanks contained within a room.

11. On or about September 7, 2021, EPA performed a compliance evaluation inspection of the Facility pursuant to Subtitle C of RCRA. Based upon the information gathered during this inspection and subsequent investigation, EPA determined that Respondent violated California Health & Safety Code § 251000, *et seq.* and the regulations adopted pursuant thereto, as approved and authorized by the United States.
12. Section 3008 of RCRA, 42 U.S.C. § 6928, authorizes the EPA Administrator to issue orders assessing a civil penalty and/or requiring compliance immediately or within a specified time for violation of any requirement of Subtitle C of RCRA, 42 U.S.C. § 6921, *et seq.*, and state regulations adopted pursuant thereto.
13. Respondent is a “person” as defined in 22 C.C.R. § 66260.10 [*see also* 40 C.F.R. § 260.10].
14. Respondent is the “owner” of a facility as defined in 22 C.C.R. § 66260.10 [*see also* 40 C.F.R. § 260.10].
15. Respondent is the “operator” of a facility as defined in 22 C.C.R. § 66260.10 [*see also* 40 C.F.R. § 260.10].
16. Respondent is a “generator” of hazardous waste as defined in 22 C.C.R. § 66260.10 [*see also* 40 C.F.R. § 260.10].
17. Respondent is or has been engaged in “treatment,” “storage,” or “disposal” of “hazardous waste” as defined in 22 C.C.R. §§ 66260.10 and 66261.3 [*see also* 40 C.F.R. §§ 260.10 and 261.3].
18. At the Facility, Respondent generates and accumulates, or has generated and accumulated, “hazardous waste,” as defined in California Health & Safety Code § 25117, and 22 C.C.R. §§ 66260.10 and 66261.2 [*see also* RCRA § 1004(5), and 40 C.F.R. §§ 260.10 and 261.2]. These hazardous wastes include but are not limited to the hazardous waste code D001.

**D. ALLEGED VIOLATIONS**

**COUNT I**

**(Failure To Comply With Air Emission Standards For Equipment Leaks)**

19. Paragraphs 1 through 18 above, are incorporated herein by this reference as if they were set forth here in their entirety.
20. 22 C.C.R. § 66270.1 [*see also* 40 C.F.R. § 270.1] requires that, with certain exceptions not relevant here, owners and operators must have interim status or obtain a permit for treatment, storage, or disposal of hazardous waste.
21. 22 C.C.R. § 66262.34(a)(1)(A) [*see also* 40 C.F.R. § 262.17(a)(1)(i)] exempts generators of hazardous waste from the permit requirements of 22 C.C.R. § 66270.1 [*see also* 40 C.F.R. § 270.1] and allows generators to accumulate hazardous waste on-site for up to 90 days provided that they meet certain conditions, including that the waste is accumulated in containers or tanks and the generator complies with the air emissions standards for equipment leaks found at Title 22, Division 4.5, Chapter 15, Article 28 (Air Emission Standards for Equipment Leaks) of the California Code of Regulations, 22 C.C.R. §§ 66265.1050-1065 (“Subpart BB”) [*see also* 40 C.F.R. §§ 265.1050-1065], if applicable.
22. Subpart BB requires generators to control air emissions from equipment that contains or contacts hazardous wastes with organic concentrations of at least 10 percent by weight, by, *inter alia*, determining percent-by-weight total organics in the hazardous waste stream, 22 C.C.R. § 66265.1063(d) [*see also* 40 C.F.R. § 265.1063(d)], marking all equipment to which the subpart applies, 22 C.C.R. § 66265.1050(d) [*see also* 40 C.F.R. § 265.1050(d)], and developing and implementing recordkeeping requirements for regulated equipment, 22 C.C.R. § 66265.1064(b)(1) [*see also* 40 C.F.R. § 265.1064(b)(1)].
23. At the time of the inspection, EPA determined that Respondent managed hazardous waste but did not have interim status or a permit to do so.
24. EPA determined that at the Facility, Respondent uses equipment that contains or contacts waste exceeding organic concentrations of at least 10 percent by weight.
25. During the inspection, EPA observed that Respondent was not implementing the Subpart BB requirements for air emissions standards for equipment leaks.
26. EPA alleges that by failing to satisfy the Subpart BB requirements, Respondent failed to meet the conditional requirement for the permit exemption and therefore is effectively operating a hazardous waste management facility without a permit in violation of 22 C.C.R. § 66270.1 [*see also* 40 C.F.R. § 270.1].

**COUNT II**  
**(Failure to Comply with Air Emission Control Standards for Tanks)**

27. Paragraphs 1 through 18 above, are incorporated herein by this reference as if they were set forth here in their entirety.
28. 22 C.C.R. § 66270.1 [*see also* 40 C.F.R. § 270.1] requires that, with certain exceptions not relevant here, owners and operators must have interim status or obtain a permit for treatment, storage, or disposal of hazardous waste.
29. 22 C.C.R. § 66262.34(a)(1)(A) [*see also* 40 C.F.R. § 262.17(a)(1)(i)] exempts generators of hazardous waste from the permit requirements of 22 C.C.R. § 66270.1 [*see also* 40 C.F.R. § 270.1] and allows generators to accumulate hazardous waste on-site for up to 90 days provided that, among other things, the waste is accumulated in containers or tanks and the generator complies with the air emissions standards found at Title 22, Division 4.5, Chapter 15, Article 28.5 (Air Emission Standards for Tanks, Surface Impoundments, and Containers) of the California Code of Regulations, 22 C.C.R. §§ 66265.1080-1090 (“Subpart CC”) [*see also* 40 C.F.R. §§ 265.1080-1090] if applicable.
30. Subpart CC applies to generators that treat or store RCRA hazardous waste in tank systems. Generators are required to control air emissions from tanks, by, *inter alia*, determining whether the average volatile organic concentration (“VOC”) of the waste exceeds 500 parts per million by weight at the point of origination, 22 C.C.R. § 66265.1084(a) [*see also* 40 C.F.R. § 265.1084(a)], installing closure devices on the roof vent, 22 C.C.R. § 66265.1085(c)(2)(C)(1) [*see also* 40 C.F.R. § 265.1085(c)(2)(iii)(A)], and developing and implementing recordkeeping requirements for regulated tanks, 22 C.C.R. § 66265.1090 [*see also* 40 C.F.R. § 265.1090].
31. At the time of the inspection, EPA determined that Respondent managed hazardous waste but did not have interim status or a permit to do so.
32. EPA determined that Respondent accumulates hazardous waste in the Waste Storage Tank and based on Respondent’s waste profiles, the waste exceeds the threshold organic concentrations.
33. During the inspection, EPA observed that Respondent was not fully implementing the air emissions standards for its Waste Storage Tank.

34. EPA alleges that by failing to satisfy the Subpart CC requirements, Respondent failed to meet the conditional requirement for the permit exemption and therefore is effectively operating a hazardous waste management facility without a permit in violation of 22 C.C.R. § 66270.1 [*see also* 40 C.F.R. § 270.1].

**COUNT III**  
**(Failure To Install A Leak Detection System)**

35. Paragraphs 1 through 18 above, are incorporated herein by this reference as if they were set forth here in their entirety.
36. 22 C.C.R. § 66270.1 [*see also* 40 C.F.R. § 270.1] requires that, with certain exceptions not relevant here, owners and operators must have interim status or obtain a permit for treatment, storage, or disposal of hazardous waste.
37. 22 C.C.R. § 66262.34(a)(1)(A) [*see also* 40 C.F.R. § 262.17(a)(1)(i)] exempts generators of hazardous waste from the permit requirements of 22 C.C.R. § 66270.1 [*see also* 40 C.F.R. § 270.1] and allows generators to accumulate hazardous waste on-site for up to 90 days provided that, *inter alia*, the waste is accumulated in containers or tanks and the generator complies with tank system standards found at Title 22, Division 4.5, Chapter 15, Article 10 (Tank Systems) of the California Code of Regulations, 22 C.C.R. §§ 66265.190-202 (“Subpart J”) [*see also* 40 C.F.R. §§ 265.190-202].
38. Subpart J also requires owners or operators to obtain a written tank system assessment that includes, *inter alia*, a description and evaluation of the leak detection equipment for the tank system, 22 C.C.R. § 66265.192(a),(k)(4) [*see also* 40 C.F.R. § 265.192(a)(1)].
39. At the time of the inspection, EPA determined that Respondent managed hazardous waste but did not have interim status or a permit to do so.
40. EPA determined that Respondent accumulates hazardous waste in the Waste Storage Tank.
41. During the inspection, EPA reviewed Respondent’s written tank assessment for the Waste Storage Tank and observed that there was no description nor evaluation of the leak detection equipment.
42. EPA alleges that by failing to fully document the Waste Storage Tank’s leak detection system in the written tank assessment, Respondent failed to meet the conditional requirement for the permit exemption and therefore is effectively operating a hazardous

waste management facility without a permit in violation of 22 C.C.R. § 66270.1 [*see also* 40 C.F.R. § 270.1].

**COUNT IV**  
**(Failure To Install Secondary Containment Devices)**

43. Paragraphs 1 through 18 above, are incorporated herein by this reference as if they were set forth here in their entirety.
44. 22 C.C.R. § 66270.1 [*see also* 40 C.F.R. § 270.1] requires that, with certain exceptions not relevant here, owners and operators must have interim status or obtain a permit for treatment, storage, or disposal of hazardous waste.
45. 22 C.C.R. § 66262.34(a)(1)(A) [*see also* 40 C.F.R. § 262.17(a)(1)(i)] exempts generators of hazardous waste from the permit requirements of 22 C.C.R. § 66270.1 [*see also* 40 C.F.R. § 270.1] and allows generators to accumulate hazardous waste on-site for up to 90 days provided that, *inter alia*, the waste is accumulated in containers or tanks and the generator complies with tank system standards found at Title 22, Division 4.5, Chapter 15, Article 10 (Tank Systems) of the California Code of Regulations, 22 C.C.R. §§ 66265.190-202 (“Subpart J”) [*see also* 40 C.F.R. §§ 265.190-202].
46. Subpart J states that tanks storing hazardous waste must be equipped with a secondary containment system which includes one of the following: an external liner, a vault, a double-walled tank, or an equivalent device approved by the California Department of Toxic Substances Control, 22 C.C.R. § 66265.193(d) [*see also* 40 C.F.R. § 265.193(d)].
47. Subpart J also requires owners or operators to obtain a written tank system assessment that includes, *inter alia*, a description and evaluation of secondary containment for the tank system, 22 C.C.R. § 66265.192(a),(k)(7) [*see also* 40 C.F.R. § 265.192(a)(1)].
48. At the time of the inspection, EPA determined that Respondent managed hazardous waste but did not have interim status or a permit to do so.
49. EPA determined that Respondent accumulates hazardous waste in the Waste Storage Tank.
50. During the inspection, EPA reviewed Respondent’s written tank assessment for the Waste Storage Tank and observed that there was inadequate documentation of a secondary containment system.

51. EPA alleges that by failing to document the Waste Storage Tank's secondary containment system in the written tank assessment, Respondent failed to meet the conditional requirement for the permit exemption and therefore is effectively operating a hazardous waste management facility without a permit in violation of 22 C.C.R. § 66270.1 [*see also* 40 C.F.R. § 270.1].

**COUNT V**  
**(Failure To Keep Daily Inspection Records)**

52. Paragraphs 1 through 18 above, are incorporated herein by this reference as if they were set forth here in their entirety.
53. 22 C.C.R. § 66270.1 [*see also* 40 C.F.R. § 270.1] requires that, with certain exceptions not relevant here, owners and operators must have interim status or obtain a permit for treatment, storage, or disposal of hazardous waste.
54. 22 C.C.R. § 66262.34(a)(1)(A) [*see also* 40 C.F.R. § 262.17(a)(1)(i)] exempts generators of hazardous waste from the permit requirements of 22 C.C.R. § 66270.1 [*see also* 40 C.F.R. § 270.1] and allows generators to accumulate hazardous waste on-site for up to 90 days provided that, among other things, the waste is accumulated in containers or tanks and the generator complies with tank system standards found at Title 22, Division 4.5, Chapter 15, Article 10 (Tank Systems) of the California Code of Regulations, 22 C.C.R. §§ 66265.190-202 ("Subpart J") [*see also* 40 C.F.R. §§ 265.190-202].
55. Subpart J requires that owners or operators must conduct daily inspections of data gathered from monitoring and leak detection equipment to ensure that the tank system is being operated according to its design. 22 C.C.R. § 66265.195(a)(3) [*see also* 40 C.F.R. § 265.195(a)] requires that these daily inspections be documented in the operating record of the facility.
56. EPA determined that Respondent managed hazardous waste but did not have interim status or a permit to do so.
57. Respondent accumulates hazardous waste in the Waste Storage Tank, Respondent is subject to the Tank System requirements.
58. During the inspection, EPA learned that Respondent had no record of such daily inspections of the Waste Storage Tank.
59. Therefore, EPA alleges that by failing to document daily inspections of monitoring and



leak detection equipment to the Waste Storage Tank, Respondent failed to meet the conditional requirement for the permit exemption and therefore is effectively operating a hazardous waste management facility without a permit in violation of 22 C.C.R. § 66270.1 [*see also* 40 C.F.R. § 270.1].

**E. CIVIL PENALTY**

60. Complainant proposes that Respondent be assessed, and Respondent agrees to pay \$250,000 (TWO HUNDRED AND FIFTY THOUSAND DOLLARS) as the civil penalty for the violations alleged herein.
61. The proposed penalty was calculated in accordance with the “June 2003 RCRA Civil Penalty Policy,” as amended by the “Amendment to the EPA’s Resource Conservation and Recovery Act (RCRA) Civil Penalty Policy to Address Generator Storage Violation Cases,” issued on May 1, 2020, and was adjusted for inflation by the Federal Civil Penalties Inflation Adjustment Act, as amended, and the Civil Monetary Penalty Inflation Adjustment Rule, 40 C.F.R. Part 19.

**F. ADMISSIONS AND WAIVERS OF RIGHTS**

62. In accordance with 40 CFR § 22.18(b), for the purpose of this proceeding, Respondent:
  - a. admits the jurisdictional allegations of this CA/FO;
  - b. neither admits nor denies specific factual allegations contained in this CA/FO;
  - c. consents to the assessment of any stated civil penalty, to the issuance of any specified compliance or corrective action order, and to any conditions specified in this CA/FO; and
  - d. waives any right to contest the allegations and its right to appeal the proposed final order accompanying this consent agreement.

**G. PARTIES BOUND**

63. This CA/FO shall apply to and be binding upon Respondent and its agents, successors and assigns, until the civil penalty required under Section E and H has been paid in accordance with Section H, and any stipulated penalties have been resolved. At such time as those matters are concluded, this CA/FO shall terminate and constitute full settlement of civil penalty liability of the violations alleged herein.
64. No change in ownership or corporate, partnership or legal status relating to the Facility will in any way alter Respondent’s obligations and responsibilities under this CA/FO.

65. The undersigned representative of Respondent hereby certifies that he or she is fully authorized by Respondent to enter into this CA/FO, to execute and to legally bind the Respondent to it.

**H. PAYMENT OF CIVIL PENALTY**

66. Respondent consents to the assessment of and agrees to pay a civil penalty \$250,000 (TWO HUNDRED AND FIFTY THOUSAND DOLLARS in full settlement of the federal civil penalty claims set forth in this CA/FO.
67. Respondent shall submit payment within thirty (30) calendar days of the "Effective Date" of this CA/FO, as that term is defined in Section N.
68. All payments shall indicate the name of the Facility, EPA identification number of the Facility (CAR000011122), Respondent's name and address, and the EPA docket number of this action. Payment made by certified or cashier's checks shall be payable to "Treasurer of the United States." Information on how to make a payment to EPA can accessed here: <https://www.epa.gov/financial/makepayment>.

A copy of each check, or notification that the payment has been made by one of the other methods listed on the website, including proof of the date payment was made, shall be sent with a transmittal letter, indicating Respondent's name, the case title, and docket number, to both:

Regional Hearing Clerk (ORC-1)  
Office of Regional Counsel  
U.S. Environmental Protection Agency - Region IX  
R9HearingClerk@epa.gov

And

Christopher Rollins (ENF-2-2)  
Enforcement and Compliance Assurance Division  
U.S. Environmental Protection Agency - Region IX  
Rollins.Christopher@epa.gov

69. Each payment must be received by the due date set forth in this CA/FO to avoid additional charges. If payment is not received by the due date, interest will accrue from the Effective Date of this CA/FO at the current rate published by the United States

Treasury as described at 40 C.F.R. § 13.11. In addition, a 6% per annum penalty assessed monthly will further apply on any principal amount not paid within ninety (90) calendar days of its due date. Respondent further will be liable for stipulated penalties as set forth below for any payment not received by its due date.

70. The penalties specified in this CA/FO shall represent civil penalties assessed by EPA and shall not be deducted by Respondent or any other person or entity for federal, state, or local taxation purposes.

#### **I. DELAY IN PERFORMANCE/STIPULATED PENALTIES**

71. In the event that Respondent fails to meet any requirement set forth in this CA/FO, Respondent shall pay stipulated penalties up to FIVE HUNDRED DOLLARS (\$500.00) per day for the first to fifteenth day of delay, up to ONE THOUSAND DOLLARS (\$1,000.00) per day for the sixteenth to thirtieth day of delay, and up to FIVE THOUSAND DOLLARS (\$5,000.00) per day for each day of delay thereafter.
72. All penalties and interest owed to EPA under this Section shall be due within thirty (30) days of receipt of a notification of noncompliance. Such notification shall describe the noncompliance and shall indicate the amount of penalties due. Interest at the current rate published by the United States Treasury, as described at 40 C.F.R. § 13.11, shall begin to accrue on the unpaid balance at the end of the thirty-day period.
73. All penalties and interest shall be remitted in the same manner described in Section H.
74. The payment of stipulated penalties shall not alter in any way Respondent's obligation to complete the performance required hereunder.
75. Notwithstanding any other provision of this Section, EPA may, in its unreviewable discretion, waive any portion of stipulated penalties that have accrued pursuant to this CA/FO.
76. The stipulated penalties set forth in this Section do not preclude EPA from pursuing any other remedies or sanctions that may be available to EPA because of Respondent's failure to comply with any of the requirements of this CA/FO.
77. The payment of stipulated penalties specified in the Section shall not be deducted by Respondent or any other person or entity for federal, state or local taxation purposes.

#### **J. CERTIFICATION OF COMPLIANCE**

78. In executing this CA/FO, Respondent certifies under penalty of law to EPA that it has fully complied with Subtitle C of RCRA, and its implementing regulations that formed the basis for the violations alleged in Section D, above.
79. This certification of compliance is based upon true, accurate, and complete information, which the signatory can verify personally or regarding which the signatory has required of the person or persons directly responsible for gathering the information.

**K. RESERVATION OF RIGHTS**

80. In accordance with 40 C.F.R. § 22.18(c), full compliance with this CA/FO shall only resolve Respondent's liability for federal civil penalties for the violations specifically alleged herein and does not in any case affect the right of the EPA to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law.
81. This CA/FO is not a permit or modification of any existing permit issued pursuant to any federal, state, or local laws or regulations. This CA/FO shall in no way relieve or affect Respondent's obligations under any applicable federal, state or local laws, regulations, or permits.

**L. OTHER CLAIMS**

82. Nothing in this CA/FO shall constitute or be construed as a release from any other claim, cause of action or demand in law or equity by or against any person, firm, partnership, entity or corporation for any liability it may have arising out of or relating in any way to the generation, storage, treatment, handling, transportation, release, or disposal of any hazardous constituents, hazardous substances, hazardous wastes, pollutants, or contaminants found at, taken to, or taken from the Facility.

**M. MISCELLANEOUS**

83. This CA/FO can be signed in counterparts.
84. This CA/FO may be amended or modified only by written agreement executed by both EPA and Respondent.
85. The headings in this CA/FO are for convenience of reference only and shall not affect interpretation of this CA/FO.

86. Each party to this action shall bear its own costs and attorneys' fees.
87. Respondent consents to entry of this CA/FO without further notice.
88. By signing this CA/FO, Respondent acknowledges that this CA/FO will be available to the public and agrees that this CA/FO does not contain any confidential business information or personally identifiable information.
89. Respondent shall complete a W-9 form <https://www.irs.gov/pub/irs-pdf/fw9.pdf> and email completed forms to [CINWD\\_AcctsReceivable@epa.gov](mailto:CINWD_AcctsReceivable@epa.gov) with encryption.

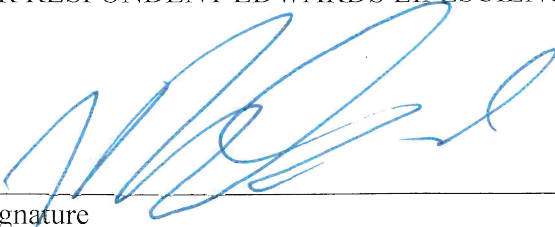
**N. EFFECTIVE DATE**

90. In accordance with 40 C.F.R. §§ 22.18(b)(3) and 22.31(b), this CA/FO shall be effective on the date that the Final Order contained in this CA/FO, signed by the Regional Judicial Officer, is filed with the Regional Hearing Clerk.

IT IS SO AGREED.

In the matter of Edwards Lifesciences, LLC  
Consent Agreement Final Order

FOR RESPONDENT EDWARDS LIFESCIENCES LLC:



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Signature

8/29/24

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Date

Joe Nuzzolese

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Print Name

Corporate Vice President, Global Supply Chain & Quality


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Title

In the matter of Edwards Lifesciences, LLC  
Consent Agreement Final Order

FOR COMPLAINANT U.S. ENVIRONMENTAL PROTECTION AGENCY, REGION:

**AMY MILLER-  
BOWEN**

 Digitally signed by AMY MILLER-  
BOWEN  
Date: 2024.09.24 09:54:56 -07'00'

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Amy C. Miller-Bowen, Director  
Enforcement and Compliance Assurance Division

**FINAL ORDER**

IT IS HEREBY ORDERED that this Consent Agreement and Final Order pursuant to 40 C.F.R. Sections 22.13 and 22.18 (U.S. EPA Docket No. RCRA-09-2024-0099) be entered and that Respondent shall pay a civil penalty of \$250,000 (TWO HUNDRED AND FIFTY THOUSAND DOLLARS) in accordance with the terms of this CA/FO.

A notice of payment and a copy of the check or other form of payment shall be sent to the EPA Region IX addresses specified in Section H of this Consent Agreement and Final Order at the time payment is made.

This Final Order shall be effective upon filing with the Regional Hearing Clerk.

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Beatrice Wong  
Regional Judicial Officer  
United States EPA Region 9



## **CERTIFICATE OF SERVICE**

I certify that the original of the fully executed Consent Agreement and Final Order in the matter of Edwards Lifesciences, LLC (Docket No. RCRA-09-2024-0099) was filed with the Regional Hearing Clerk, U.S. EPA, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, and that a true and correct copy of the same was served on the parties, via electronic mail, as indicated below:

**RESPONDENT:**

Priya Karipalli  
Edwards Lifesciences, LLC  
One Edwards Way  
Irvine, CA 92614  
[Priya\\_karipalli@edwards.com](mailto:Priya_karipalli@edwards.com)

Adam G. Sowatzka, Esq.  
McGuire Woods, LLP  
1075 Peachtree Street, N.E., 35<sup>th</sup> Floor  
Atlanta, GA 30309-3900  
[Asowatzka@mcquirewoods.com](mailto:Asowatzka@mcquirewoods.com)

**COMPLAINANT:**

Emily Griffith, Attorney Advisor  
U.S. Environmental Protection Agency, Region IX  
75 Hawthorne Street  
San Francisco, CA 94105  
[Griffith.Emily@epa.gov](mailto:Griffith.Emily@epa.gov)

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Ponly Tu  
Regional Hearing Clerk  
U.S. EPA – Region IX