Provisional Translation (as of August 2025).
This English document has been prepared for reference purpose only. In the event of inconsistency and discrepancy between the Japanese original and the English translation, the Japanese text shall prevail.

User fees for PMDA inspection of medical devices and in vitro diagnostics based on the Act on Securing of Safety of Regenerative Medicine (Act No. 85, 2013)

Note) The applicable articles of the Act on Securing of Safety of Regenerative Medicine (Cabinet Order No. 278) are shown in the lower rows in the column of user fees. (unit: yen)

Category			Conformity	Total
Assessment for manufacturing license of specific cellular products				
	New license	On-site	144,000	144,000
			Article 8, Paragraph 1, Item 1	
		Document-based	98,200	98,200
			Article 8, Paragraph 1, Item 2	
	Renewal of existing license	On-site	97,100	97,100
			Article 8, Paragraph 2, Item 1	
		Document-based	48,600	48,600
			Article 8, Paragraph 2, Item 2	
Assessment for accreditation for manufacturing of specific cellular products				
	New accreditation	On-site	120,500 + overseas travel expenses	120,500 + overseas travel expenses
			Article 8, Paragraph 3, Item 1	
		Document-based	54,200	54,200
			Article 8, Paragraph 3, Item 2	
	Renewal of existing accreditation	On-site	56,500 + overseas travel expenses	56,500 + overseas travel expenses
			Article 8, Paragraph 4, Item 1	
		Document-based	37,100	37,100
			Article 8, Paragraph 4, Item 2	