Friday, 24 July 2026

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A-601, Marathon Innova, Opp. Peninsula
Corporate Park, Off Ganpatrao Kadam Marg,
Lower Parel (W), Mumbai 400 013, India.

Tel.:+91-22-6673 6800,
Fax: 91-22-66399727
web: www.sidvim.com

UPCOMING EVENTS

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This year's Asia Bio Partnering Forum program explores the trends, partnerships, and commercial strategies shaping APAC's evolving life sciences ecosystem, from biotech partnering and investment to clinical development and global expansion.

New for 2026, a dedicated Medtech track will run alongside the core Asia Bio Partnering Foum program, creating additional opportunities for cross-sector networking, collaboration, and discussion around the future of healthcare innovation in Asia-Pacific.

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- The Future of Healthcare Innovation in APAC: Scaling, Partnering & Global Growth
- Where Capital Meets Opportunity - APAC Dealmaking in 2026
- License, Co-Develop, or Build? Rethinking Partnership Models
- Building an APAC Biotech for Global Growth
- East Meets West: Cross-Border Partnerships, Investment & Global Expansion
- What Pharma Really Wants: Partnering Priorities for 2026
- From Data to Deal: Making APAC Clinical Data Globally Actionable
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MEDTECH PLENARY SESSIONS

- Spotlight on Medtech in the Asia Pacific: Opportunities, Challenges, and the Path Forward
- Unlocking Strategic Partnerships: How to Engage Tier 1 Medtech and Pharma's Biggest Players
- Securing Family Office Investment: Medtech and Digital Health Startups
- Innovations in Medtech: Ageing, Diagnostics, Neuro & Robotics
- Harmonizing Medtech Regulations in the Asia Pacific: Feasibility, Timelines, and Progress
- Breaking Into the US Market: A Roadmap for Asia Pacific Medtech Startups
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DEALS AND FUNDING

Samsung Biologics agrees $1.81bn takeover of PolyPeptide

Pharmaphorum, 20th July 2026

In what is thought to be South Korea's largest biopharma acquisition to date, Samsung Biologics has agreed to buy PolyPeptide, a Swiss contract development manufacturing organisation (CDMO) specialising in peptide drugs.

The CHF 1.46 billion ($1.81 billion) all-cash bid has been made at CHF 44.31 per share – the stock is currently trading up 5.3% at CHF 43.85 – and marks Samsung Biologics' first entry into the peptide manufacturing category. This is currently red hot, being driven by the juggernaut growth of drugs like GLP-1 agonists for weight loss and diabetes.

Rumours of takeover interest in PolyPeptide have been circulating for a few months, and the offer is a 40% premium to the company's share price in April when speculation started in earnest.

Incheon-headquartered Samsung Biologics is a CDMO that, as its name indicates, specialises in biologic medicines like antibodies and antibody-drug conjugates (ADCs) and works with 17 of the top 20 global pharmaceutical firms, making revenues of around $3.5 billion last year.

For comparison, PolyPeptide revenues were €389 million last year, up more than 15%, which the company said was "driven by strong peptide metabolic demand," and the company has said it is modelling 25% to 30% revenue growth this year, and a doubling in its annual turnover by 2028.

This acquisition reinforces our long-term growth strategy by not only broadening our service portfolio with modality expansion into peptides, including GLP-1, but by also boosting our geographic reach and proximity further within the US, Europe, and India," said the Korean company's chief executive, John Rim.

PolyPeptide operates several sites across Sweden, Belgium, France, the US, and India, together with a corporate office in Switzerland and a separate innovation centre in Strasbourg, France.

The boards of both companies have approved the transaction, which is expected to close by the end of the year and will kick off with a tender offer next month. If all goes to plan and the deal completes, which requires a two-thirds majority ownership, Samsung Biologics will try to claim 100% control and delist PolyPeptide from the Swiss stock exchange.

We have transformed PolyPeptide into one of the leading focused peptide CDMOs globally, with a rich pipeline, deep exposure to the fast-growing metabolics space, and a marked acceleration in sales growth and profitability," said PolyPeptide CEO Juan Jose Gonzalez.

Samsung Biologics agrees $1.81bn takeover of PolyPeptide

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Akums To Acquire Oriflame India's Manufacturing Business

BW Healthcare, 24th July 2026

Akums Drugs and Pharmaceuticals has entered into an agreement through its wholly owned subsidiary, Pure and Cure Healthcare, to acquire the manufacturing business of Oriflame India for Rs56 crore, following board approval. The acquisition marks Akums' entry into the color cosmetics manufacturing segment while strengthening its position in India's growing cosmetics contract development and manufacturing (CDMO) market. Approved by the board on July 23, 2026, the transaction includes two manufacturing facilities located in Roorkee, Uttarakhand, and Noida, Uttar Pradesh, along with a leased warehouse in Noida. The acquisition is being undertaken through an all-cash transaction and is expected to be completed by August 31, 2026, subject to customary closing conditions.

The facilities bring manufacturing capabilities across skincare, wellness, hair care and color cosmetics. They are equipped to produce creams, lotions, scrubs, face washes, serums, shampoos, conditioners, lipsticks, foundations, primers, mascaras and eyeliners. Both manufacturing units are equipped with European-made processing, filling and labelling machinery and support production across multiple batch sizes. The facilities are also Halal certified, enabling export opportunities.

The transaction is limited to Oriflame India's manufacturing operations. The company's marketing, sales and trademark rights in India will remain with Oriflame India and are not part of the acquisition.The company said the acquisition will significantly expand its existing skincare and wellness manufacturing business while establishing a presence in the rapidly growing color cosmetics category.

India's cosmetics market, currently estimated at around USD 20 billion, is expected to witness strong growth over the coming years, driven by increasing demand for premium beauty products, rising self-care awareness, expansion of e-commerce and omnichannel retail, and the growing influence of social media and beauty influencers. Commenting on the acquisition, Sanjeev Jain, Managing Director, Akums Drugs and Pharmaceuticals ,

said the deal represents an important milestone in the company's diversification strategy. He noted that color cosmetics is among the fastest-growing consumer categories in India and that the acquisition provides Akums with established manufacturing capabilities to serve both domestic and international brands.

Sandeep Jain, Managing Director, Akums Drugs and Pharmaceuticals Limited, said the Roorkee and Noida facilities complement the company's existing manufacturing infrastructure and create operational synergies. He added that the company aims to strengthen its position as a world-class cosmetics CDMO catering to both Indian and export markets.

Akums To Acquire Oriflame India's Manufacturing Business

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PHARMA & BIOLOGICS

SMALL MOLECULES

Global isonipecotic acid market set for robust growth through 2035 on pharmaceutical and specialty chemicals demand

ETChemicals, 23rd July 2026

The global isonipecotic acid market is forecast to grow steadily through 2035, driven by pharmaceutical API demand and expanding specialty chemical applications, with Asia-Pacific supply reshaping trade flows and compliance standards.

As pharmaceutical innovation accelerates and specialty chemical applications expand, isonipecotic acid is emerging as a strategic molecule underpinning multiple high-growth sectors. Industry forecasts indicate that the global market for isonipecotic acid, a piperidine-4-carboxylic acid compound, is on track for steady expansion through 2035, propelled by increased demand from the pharmaceutical, agrochemical, and advanced materials industries.

Strategic role in global pharmaceutical manufacturing

Isonipecotic acid is best known as a critical intermediate in the synthesis of active pharmaceutical ingredients (APIs) for opioid analgesics, antihistamines, and a range of cardiovascular medications. According to market research from IndexBox, pharmaceutical intermediates currently account for roughly 60 per cent of global isonipecotic acid consumption. The compound's importance is growing as the prevalence of chronic pain conditions rises worldwide, coupled with an ageing population and greater access to advanced pain management therapies in emerging economies.

Global pharmaceutical manufacturing trends have further supported demand. The ongoing shift towards contract manufacturing and outsourcing of API production, particularly to India and China, has created strong pull for high-purity, GMP-compliant isonipecotic acid. As regulatory scrutiny intensifies in major markets, the premium segment for certified grades is experiencing annual growth rates of 6 to 8 per cent, as reported by IndexBox.

https://chemicals.economictimes.indiatimes.com/news/pharma-chemicals/global-isonipecotic-acid-market-set-for-robust-growth-through-2035-on-pharmaceutical-and-specialty-chemicals-demand/132581852

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Aspen's Generic Ozempic Gets Health Canada Approval, Launch Hinges on Dr Reddy's API Supply

Medicaldialogues, 21st March 2026

South Africa's Aspen Pharmacare said on Monday that its Canadian subsidiary had received regulatory approval from Health Canada for Aspen-Semaglutide, a generic version of Novo Nordisk's blockbuster diabetes drug Ozempic.

Africa's biggest pharmaceutical company said in a statement that its generic semaglutide is authorized for the management of type 2 diabetes.

The expiry of Novo's patent for semaglutide, the active ingredient in the Danish drugmaker's blockbuster GLP-1 drugs Ozempic for diabetes and Wegovy for weight loss, has opened the door for several drugmakers looking to enter the Canadian market with generic versions, which are essentially copies of branded drugs.

The timing of Aspen's commercial launch in Canada remains dependent on the availability of semaglutide active pharmaceutical ingredient (API) supply from India's Dr. Reddy's Laboratories, the company said.

https://medicaldialogues.in/amp/news/industry/pharma/aspens-generic-ozempic-gets-health-canada-approval-launch-hinges-on-dr-reddys-api-supply-175467

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LARGE MOLECULES

India approves first dengue vaccine for individuals aged 4 to 60 years

Takeda's two-dose QDENGA vaccine, approved by the Drug Controller General of India, can be administered without prior dengue screening and is designed to protect against all four dengue virus serotypes

The Hindu, 20 July 2026

The Drug Controller General of India (DCGI) has granted market authorisation to Takeda Biopharmaceuticals India's QDENGA (TAK-003), making it the first dengue vaccine to be approved in the country, according to a press release issued by the company.

The vaccine has been approved for the prevention of dengue disease in individuals aged 4 to 60 years. QDENGA is a live-attenuated tetravalent vaccine designed to provide protection against all four dengue virus serotypes and is administered as a two-dose regimen, with doses given three months apart.

According to the company, the vaccine can be administered irrespective of whether an individual has had a previous dengue infection and does not require pre-vaccination screening. The approval comes as dengue continues to pose a significant public health challenge in India, where reported cases have increased nearly 11-fold over the past two decades. India accounts for nearly one-third of the global dengue burden, although modelling studies suggest the actual number of infections is substantially higher than reported.

The approval is based on Takeda's global clinical development programme comprising 19 Phase I, II and III clinical trials involving more than 28,000 participants in dengue-endemic and non-endemic regions. The company's pivotal Phase III TIDES (DEN-301) trial enrolled more than 20,000 participants across eight dengue-endemic countries.

According to Takeda, the vaccine demonstrated an efficacy of 80.2% against virologically confirmed dengue 12 months after the second dose and 90.4% efficacy against dengue-related hospitalisation at 18 months. Follow-up data at 4.5 years showed 84.1% efficacy against dengue-related hospitalisation, while seven-year follow-up demonstrated sustained protection against dengue disease and dengue-related hospitalisation across all four serotypes.

India approves first dengue vaccine for individuals aged 4 to 60 years - The Hindu

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Kolon's cell-based gene therapy fails phase 3 osteoarthritis trial

Fierce Pharma, 20th July 2026

A phase 3 trial of Kolon TissueGene's cell-based gene therapy has missed its co-primary endpoints. With a second late-stage study scheduled to report data in October, the biotech is holding off on determining the next steps for the osteoarthritis candidate.

The failed phase 3 trial tested TG-C, a drug candidate containing human allogeneic chondrocytes and an irradiated human embryonic kidney-derived cell line stably expressing TGF-β1. Authorities in South Korea authorized the medicine in 2017, only to retract the approval two years later over a mix-up regarding the type of cells used in the therapy.

Seeking to validate the candidate, Kolon enrolled 531 people with osteoarthritis of the knee at 27 sites in the U.S. The study, which was delayed by an FDA hold and began enrolling patients four years after Kolon registered the trial, compared intra-articular injections of the cell-based gene therapy and placebo. One year after the injections, recipients of TG-C performed statistically no better on assessments of knee function and pain than their peers on placebo, causing the study to miss its co-primary endpoints. The study also missed all its key secondary endpoints.

Attention now turns to the expected October delivery of data from Kolon's other phase 3 trial. The trials are similar, with the ongoing study having the same arms and co-primary endpoints as the failed trial, as well as nearly identical inclusion/exclusion criteria. Kolon will decide on the future of the program after seeing data from the second phase 3 trial. The failure of Kolon's first study adds to the list of setbacks encountered by companies trying to treat osteoarthritis of the knee. Ampio Pharmaceuticals ran into multiple obstacles before deciding to shut down in 2024. Centrexion Therapeutics CNTX-4975 failed to beat placebo in a phase 3 trial. More positive stories include Flexion Therapeutics, which won FDA approval in 2017 and was acquired in 2021.

Kolon's cell-based gene therapy fails phase 3 osteoarthritis trial

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Lilly's triple-G drug hits 22.6% weight loss, but impact on reducing cardio risk is less clear

Fiercebiotech, 22nd July 2026

Eli Lilly's triple-G drug retatrutide has hit the primary endpoints of a pair of phase 3 obesity trials, although the peak weight loss fell short of previous trials in different patient

populations while failing to prove the medication reduces cardiovascular risk.

The pharma evaluated various doses of the GIP, GLP-1 and glucagon triple-hormone receptor agonist against placebo in both the TRIUMPH-2 study of 1,152 patients with type 2 diabetes and obesity or overweight, as well as the TRIUMPH-3 study of 1,949 patients with severe obesity and established cardiovascular disease.

When looking at the efficacy estimand—which assesses data based on patients who stayed on the trial regimen without starting other "prohibited" weight loss treatments—patients in TRIUMPH-2 receiving the 12 mg dose of retatrutide saw 20.8% weight loss at 80 weeks, compared to 3.2% among the placebo cohort.

https://www.fiercebiotech.com/biotech/lillys-triple-g-drug-hits-226-weight-loss-cardio-risk-impact-disappoints

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Agios says adios to sickle cell program over lackluster phase 2 data

Fiercebiotech, 21st July 2026

A phase 2 study of Agios Pharmaceuticals' next-generation pyruvate kinase (PK) activator has failed to support continued development in sickle cell disease (SCD), leading the company to ax an indication for the second time in two months.

The phase 2 trial randomized 59 people with SCD to receive one of three daily oral doses of tebapivat or placebo. Like Agios' FDA-approved hemolytic anemia drug Pyrukynd, tebapivat is designed to upregulate PK, a key enzyme in glucose metabolism. Evidence that activating the enzyme reduces sickling of red blood cells has fueled development of PK activators in SCD.

Pyrukynd is awaiting FDA approval in SCD, despite generating mixed data, and Novo Nordisk's etavopivat hit the mark in a phase 3 trial in the indication. But Agios bet that structural features designed to enable once-daily administration, without the need for a dose taper, would differentiate tebapivat.

https://www.fiercebiotech.com/biotech/agios-says-adios-sickle-cell-program-over-lackluster-phase-2-data

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REGULATORS AND REGULATORY ACTIONS

GPCB orders closure of Aarti Drugs' Saykha amines plant over environmental non-compliances

Indianpharmapost, 20th July 2026

Aarti Drugs Limited has received closure directions from the Gujarat Pollution Control Board (GPCB), requiring it to shut manufacturing operations at its amines plant in Saykha Industrial Estate, Bharuch, Gujarat, following observations of environmental non-compliances during a regulatory inspection.

In a regulatory filing, the company said the closure order, issued under Section 33A of the Water (Prevention and Control of Pollution) Act, 1974, mandates the closure of manufacturing operations at Plot Nos. DP-94 to DP-96, Saykha Industrial Estate, with effect from 15 days from July 18, 2026, the date on which the communication was received.

The GPCB's action follows an inspection conducted on June 20, 2026, during which the regulator observed certain non-compliances relating to the Water Act and the conditions stipulated under the plant's Consolidated Consent and Authorization (CCA).

The company stated that there is no immediate impact on its financial, operational or other business activities as the closure will become effective only after the stipulated 15-day period.

https://www.indianpharmapost.com/news/gpcb-orders-closure-of-aarti-drugs-saykha-amines-plant-over-environmental-non-compliances-20988

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CDSCO proposes to ban "Same Brand, Different Drug" practice

Expresspharma, 21st July 2026

Regulator introduces "One Brand – One Formulation" policy to improve patient safety and reduce medication errors

In a landmark move aimed at strengthening medication safety and improving transparency in the pharmaceutical sector, the Central Drugs Standard Control Organisation (CDSCO) has proposed a new regulatory framework based on the principle of "One Brand – One Formulation."

The draft notification, issued for public comments on 6 July 2026, seeks to prohibit pharmaceutical companies from marketing different medicines under the same or

deceptively similar brand names—a practice that has increasingly contributed to prescribing, dispensing, and patient medication errors.

However, this was due since 2012. It was pointed out in the 59 th Parliamentary Committee Report on working of CDSCO which was submitted to the government on 8th May 2012.

Background

According to CDSCO, confusion arising from similar brand names has become one of the important causes of medication errors in India. Patients, pharmacists, and even healthcare professionals may mistakenly assume that medicines carrying the same brand name contain identical active ingredients.

Several examples have highlighted the seriousness of the problem.

- **AZ** has been marketed by different manufacturers for Cetirizine, Albendazole, and Azithromycin, three medicines used for entirely different clinical conditions.
- **Linamac** has been marketed for diabetes, whereas Linamac 5 was introduced for a cancer medication, a matter that attracted the attention of the National Human Rights Commission (NHRC).

https://www.expresspharma.in/cdsco-proposes-to-ban-same-brand-different-drug-practice/

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FDA issues untitled letters to Sanofi and Viatris for false advertising

RAPS, 22nd July 2026

The FDA's Office of Prescription Drug Promotion recently reprimanded Sanofi and Viatris for making misleading claims about their products in emails and a television advertisement.

Sanofi

FDA issued an untitled letter to Sanofi in Morristown, NJ, concerning misleading claims made in an email regarding its drug, Beyfortus (nirsevimab-alip). Beyfortus is a long-acting monoclonal antibody injection intended to prevent lower respiratory tract disease caused by respiratory syncytial virus (RSV) in newborns and infants.

The agency indicated that the company's advertisements created a misleading impression by suggesting that Beyfortus can be used for the general prevention of RSV, including

both upper and lower respiratory tract diseases, which is incorrect.

FDA has approved this product to prevent RSV in the lower respiratory tract, not in both respiratory tracts.

Viatris

FDA also issued an untitled letter to Viatris regarding the promotional claims made in a direct-to-consumer TV advertisement for its TOBI Podhaler (tobramycin inhalation powder). This prescription aminoglycoside antibiotic is used to treat chronic lung infections caused by pseudomonas aeruginosa in adults and children aged six years and older who have cystic fibrosis.

The agency disputed the advertisement's claim that the product is portable and can be administered quickly, such as in a car.

https://www.raps.org/resource/fda-issues-untitled-letters-to-sanofi-and-viatris-for-false-advertising.html

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USFDA Issues One Observation After Routine cGMP Inspection at Cipla's InvaGen Facility in New York

Pharmatutor, 21st July 2026

Cipla Limited has informed the stock exchanges that the United States Food and Drug Administration (USFDA) conducted a routine current Good Manufacturing Practices (cGMP) inspection at the manufacturing facility of its wholly owned subsidiary, InvaGen Pharmaceuticals Inc., located in Central Islip, Long Island, New York, USA.

The inspection was carried out from July 13 to July 17, 2026 (EDT) as part of the USFDA's routine regulatory oversight of pharmaceutical manufacturing facilities.

At the conclusion of the inspection, the USFDA issued one inspectional observation to the facility in the form of a Form 483.

Cipla stated that it is committed to working closely with the USFDA and will address the observation comprehensively within the stipulated timeline.

https://www.pharmatutor.org/pharma-news/2026/usfda-issues-one-observation-after-routine-cgmp-inspection-at-ciplas-invagen-facility-in-new-york

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GSK secures first lung cancer approval as FDA clears Jideytro in quick payoff from Nuvalent deal

Fierce Pharma, 22nd July 2026

In a landmark moment for its oncology ambitions, GSK has secured FDA approval for Jideytro (zidesamtinib) as the first commercial lung cancer drug in the company's history.

The milestone was made possible by GSK's recent acquisition of Nuvalent for $10.6 billion. The approval for Jideytro comes just a week after the British pharma closed the deal and about two months ahead of the FDA's target decision date of Sept. 18.

The green light allows Jideytro to treat adult patients with advanced ROS1-positive non-small cell lung cancer who received a prior ROS1 inhibitor.

"The rapid progression of Jideytro from development to approval reflects both the strength of the underlying science and the urgent need for additional effective and tolerable treatments for ROS1-positive lung cancer," GSK's chief scientific officer, Tony Wood, said in a July 22 statement.

By GSK's estimate, about 50,000 new cases of ROS1-positive NSCLC are diagnosed each year worldwide, mostly among non-smokers in their 40s and 50s who could stay on treatment for several years.

https://www.fiercepharma.com/pharma/gsk-secures-first-ever-lung-cancer-fda-approval-jideytro-nuvalent-deal

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MEDTECH

Resmed ventilator safety issue linked to 5 serious injuries

Medtech Dive, 20th July 2026

Dive Brief:

- Resmed has contacted customers about a ventilator issue linked to five serious injuries, the Food and Drug Administration said Wednesday.
- A subset of Astral 100 and Astral 150 ventilators can inadvertently enter a fail-safe state and stop delivering therapy, creating a risk of serious injury or death.
- Resmed informed customers of the issue on June 25, asking them to continue using the devices with precautions. The FDA shared the message in an early alert notification last week.

Dive Insight:

The notices relate to Astral 100 and 150 ventilators with supercapacitors that may leak overtime. If the component leaks, it can damage circuitry on the printed circuit board assembly and cause the device to enter a fail-safe state. Devices that enter that state while in use stop delivering therapy. If the device is on standby when it enters the state, it will not deliver therapy the next time the user initiates treatment.

"Patients who are unable to maintain spontaneous ventilation, or who do not have access to adequate monitoring or alternative ventilation, may be at risk of serious injury or death if the fail-safe state is entered and therapy is not restored," the FDA said.

As of June 23, Resmed had reported five serious injuries and no deaths associated with the issue, the FDA said. Resmed's letter to customers noted five reports of adverse events, one of which was serious. All patients recovered after intervention, Resmed said. The company's analysis of global post-market and service data found that about 0.1% of devices suffer leaks that cause them to enter a fail-safe state.

To prevent further incidents, Resmed is working to correct all affected ventilators. However, the supply of the circuit boards needed to fix the devices is significantly constrained, preventing the company from immediately correcting all affected ventilators.

Resmed ventilator safety issue linked to 5 serious injuries | MedTech Dive

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Johnson & Johnson Receives FDA Market Authorization in the U.S. for its OTTAVA™ Robotic Surgical System

Johnson & Johnson, 22nd July 2026

Johnson & Johnson today announced that the U.S. Food and Drug Administration (FDA) has granted De Novo authorization for the OTTAVA™ Robotic Surgical System, the world's first table-integrated soft tissue robotic system. The system received marketing authorization for multiple procedures in general surgery, including Roux-en-Y gastric bypass, gastrectomy, cholecystectomy, splenectomy, gastric sleeve, small bowel resection, appendectomy, lysis of adhesions, fundoplication, and hiatal hernia repair.

"We are pioneering a new category of surgical robotics with OTTAVA," said Tim Schmid, Executive Vice President, Worldwide Chairman, MedTech, Johnson & Johnson. "This is the start of the next era in surgery as we deliver not just a new surgical robotics system, but a catalyst for fundamentally better surgical care that is informed by technology, guided by clinical insight, and delivered with care by Johnson & Johnson."

Johnson & Johnson will commercially launch the OTTAVA system with select customers in the U.S., focusing on early customer success while working in parallel to advance into additional indications and regulatory jurisdictions over time. A U.S. clinical trial for OTTAVA in inguinal hernia procedures is ongoing.

OTTAVA is purpose-built to advance surgery today and where it goes next. Its unique architecture, automated features, next-generation robotic surgical instruments, and connection to an open digital ecosystem create a foundation to fit seamlessly into operating rooms today – and support more digitally enabled, data-driven surgery in the future.

"Surgical robotics will play an increasingly important role in surgical care, but it's clear that what defined the last 25 years of surgery will not define the next 25," said Hani Abouhalka, Company Group Chair, Surgery, MedTech, Johnson & Johnson. "By opening up the way we think about architecture, data, and the very workflows of surgery itself, we have designed OTTAVA to deliver clinical and economic benefits and support surgeons and hospitals as the future of surgery unfolds."

Johnson & Johnson Receives FDA Market Authorization in the U.S. for its OTTAVA™ Robotic Surgical System

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INTERESTING MEDICAL NEWS

Stop Testing Vitamin D in Healthy Patients, Says the Society That Told You to Start

Medscape, 23 July 2026

A 25-hydroxyvitamin D [25(OH)D] comes back at 22 ng/mL. The patient is asymptomatic. Ten years ago you'd have called that insufficient and started a supplement. Today, the same number might not even exist as a category — because in 2024, the Endocrine Society dropped the 30 ng/mL sufficiency target it wrote in 2011, and told physicians to stop routinely testing healthy adults altogether (JCEM)

Nobody updated the annual physical order set. Vitamin D remains one of the most-ordered labs in American primary care, and testing volume hasn't meaningfully budged since the reversal. That gap between what the guideline says and what the requisition form does is where the breakdown occurs.

What actually changed

The 2024 guideline (JCEM) is narrower than its 2011 predecessor in almost every direction. For healthy adults under 75, it suggests against supplementing beyond the standard Recommended Dietary Allowance (RDA) (600–800 IU/day) and against routine 25(OH)D testing — including in patients with obesity or darker skin pigmentation, two groups the 2011 version flagged for testing.

It also declines to name any target blood level for disease prevention, because, as guideline chair Marie Demay, MD, of Harvard Medical School and Massachusetts General Hospital put it when the guideline dropped: "we do not recommend routine testing for vitamin D levels in any of these groups" — referring to children, pregnant patients, adults 75 and older, and people with prediabetes, the four groups the guideline does carve out for empiric, no-testing supplementation (Endocrine Society).

The evidence base behind the reversal is four large, concordant, null trials: VITAL in the US (25,871 adults, no reduction in cancer or cardiovascular events) (NEJM), D-Health in Australia, FIND in Finland, and — the one that kills the "the null trials were all American" objection — DO-HEALTH, a five-country European trial of 2,000 IU/day in adults 70 and older that found no benefit on fractures, infections, blood pressure, physical performance, or cognition, even though 40% of participants started out deficient (JAMA, UEF Connect). USPSTF has landed in the same place for over a decade, calling the evidence on screening asymptomatic adults insufficient to weigh benefits against harms — first in 2014, again in 2021 (USPSTF).

Two camps, one number, no resolution

This isn't a new fight — it's a rematch. In 2011, the Institute of Medicine (IOM) set adequacy at ≥20 ng/mL, covering 97.5% of the population, and explicitly warned that higher cut-points were overstating how much deficiency actually existed (NAM/NCBI). The Endocrine Society's own 2011 guideline disagreed, setting sufficiency at ≥30 ng/mL based on calcium-absorption and parathyroid hormone (PTH) suppression data (JCEM).

The 2024 guideline effectively sides with the IOM — and Michael Holick, MD, PhD, the Boston University endocrinologist who chaired the 2011 guideline, has pushed back hard, arguing the newer document leaned too exclusively on RCTs and discounted decades of association data linking low vitamin D to "poor pregnancy outcomes, early childhood dental caries, increased risk for autoimmune disorders, increased risk for upper respiratory tract infections including COVID-19, advancement of prediabetes to type 2 diabetes, cardiovascular disease, neurocognitive dysfunction, mortality and accelerating mortality from deadly cancers" (Endocrine Practice).

Neither side has a trial that randomized patients to different serum targets — the entire dispute rests on how to weight the same PTH and absorption data. That's genuinely unresolved, and it's worth knowing which camp your specialist colleagues are in before you argue with them about a 24 ng/mL result.

Four groups still get vitamin D, no blood draw required

The 2024 guideline carves out empiric, higher-than-RDA supplementation, without testing, for:

- Children and adolescents (1–18): to prevent rickets and possibly reduce respiratory infections.
- Pregnant patients: potential reduction in pre-eclampsia, preterm birth, and neonatal mortality.
- Adults 75 and older: a modest mortality signal.
- Adults with high-risk prediabetes: to slow progression to diabetes.

The prediabetes call is the one worth pressure-testing. It rests on a pooled analysis of three trials showing a 15% relative reduction in progression (about 3 percentage points absolute over three years — a number needed to treat (NNT) near 30) (Endocrine Society JCEM). But every one of those trials was null on its own primary endpoint, and one used an active vitamin D analogue rather than the cholecalciferol (vitamin D3, the supplement form) you'd actually prescribe.

The American Diabetes Association has seen the same pooled data and still won't issue a positive recommendation, citing uncertain risk-benefit at the doses studied (ADA). Two major US bodies, same trials, different conclusions — that's a live disagreement, not a rounding error.

Where testing still earns its keep

The "don't test the healthy" message has a hard boundary, and it's the same boundary the 2011 guideline drew: chronic kidney disease (CKD), malabsorption (celiac, inflammatory bowel disease (IBD), bariatric surgery), granulomatous disease, hepatic failure, and patients on enzyme-inducing medications. None of that changed in 2024 — the new guideline narrows testing in the general population, not in patients with an actual reason for impaired vitamin D metabolism.

The wildcard: multiple sclerosis

The newest data point complicates the tidy "avoid high-dose bolus dosing" rule. The D-

Lay MS trial, published in JAMA in 2025, gave patients with clinically isolated syndrome (CIS) either 100,000 IU of cholecalciferol (vitamin D3) every two weeks or placebo, for 24 months. Disease activity — relapse or new MRI lesions — occurred in 60.3% of the vitamin D group versus 74.1% on placebo (HR 0.66 [95% CI, 0.50–0.87]; P=0.004; NNT 7.2) (JAMA).

Two caveats keep it from being a mandate. The result was carried by MRI lesion counts, not clinical relapse rate, which didn't reach significance on its own (17.9% vs. 21.8%; HR 0.69 [95% CI, 0.42–1.16]; P=0.16). And it's a single trial in a narrow population — recent clinically isolated syndrome, not established or progressive relapsing-remitting multiple sclerosis (RRMS). It's a reason to check and correct vitamin D in a patient with a new demyelinating event. It is not evidence for population-wide high-dose dosing.

Bottom line

Don't screen asymptomatic, otherwise healthy adults for vitamin D — the evidence against benefit is now large, international, and consistent.

For patients already taking 1000–4000 IU/day of vitamin D on their own, there is no trial evidence of harm at these doses, and advising a return to the standard RDA is reasonable but not mandatory — the guideline addresses testing and new empiric prescribing, not existing supplementation.

Patients with obesity or darker skin pigmentation who have been tested do not require routine retesting; absent a new clinical indication, no further workup is needed regardless of prior results.

Do supplement, without testing, in kids, pregnancy, patients 75 and up, and prediabetes (while knowing the ADA doesn't fully endorse that last one). Keep testing where a real disease process makes deficiency plausible: CKD, malabsorption, granulomatous disease. And if a patient presents with a first demyelinating event, checking and correcting vitamin D now has trial support behind it — nowhere else does an intermittent high-dose bolus.

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