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I push from outside, I build the argument, and once there is enough pressure through industry and society, the institutions follow

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Hong Kong is at a strategic inflection point as it seeks to redefine its role in global life sciences through regulatory credibility, institutional design, and long-term positioning between China and international markets. Industry stalwart Lo Yuk Lam reflects on how regulation, talent, capital markets, and national planning intersect to shape that ambition, and why an independent regulator for Hong Kong sits at the centre of this recalibration.

What strategic purpose does the establishment of the Centre for Medical Products Regulation (CMPR), an independent regulatory body for Hong Kong, serve in the city's life sciences ambitions, and how does it relate to China's push to globalise innovation?

The establishment of the Centre for Medical Products Regulation (CMPR) was formally set out in the Hong Kong Government's 2023 Policy Address as part of a long-term shift toward primary evaluation of medicines and medical devices. While the policy announcement was recent, the underlying debate has been ongoing for years. At its core is a question of whether Hong Kong should develop an internationally credible regulatory capability that goes beyond reliance on external authorities and reflects its growing role in biomedical innovation.

This question has gained urgency as China's life sciences sector has evolved at remarkable speed. Across pharmaceuticals, medical devices, diagnostics, artificial intelligence, and robotics, Chinese

companies are no longer limited to incremental development. They are generating original innovation and increasingly competing at the global frontier. Yet global market access remains inseparable from regulatory trust. China's regulator, the National Medical Products Administration (NMPA), plays a central role domestically, but international recognition takes time to build and remains uneven.

Hong Kong's relevance lies in its institutional positioning under the "one country, two systems" framework. The intention behind CMPR is to create a regulatory platform aligned with international standards that can support Chinese innovation as it moves outward, without compromising scientific rigour. This is not a shortcut around safety or efficacy. On the contrary, credibility must be earned through data, transparent processes, and consistent application of standards. Hong Kong is starting from a limited base in primary regulation, so recognition will be gradual rather than immediate.

The concept did not emerge in isolation. Similar discussions have taken place within mainland China among policymakers and industry leaders focused on regulatory reform and raising global standards for Chinese biotech. CMPR reflects that broader trajectory, offering Hong Kong as a bridge rather than an alternative system.

Policy frameworks alone are insufficient without people who can operate them. Alongside advocacy for CMPR, efforts have therefore focused on building regulatory science and leadership capability. A dedicated training initiative was launched to expose professionals, students, and public-sector participants to international regulatory systems and harmonisation principles. The aim is to develop talent that understands both Hong Kong's environment and global expectations, ensuring that as CMPR evolves, it rests on a credible and sustainable foundation.

What are the key conditions Hong Kong must meet to build international regulatory credibility, and how do you reconcile global ambition with the primacy of patient safety?

If Hong Kong intends to build a regulator that commands global respect, the starting point must be people rather than policy statements. International recognition cannot be achieved through designation alone; it depends on whether those assessing medicines and medical devices are trained to the standards expected by the world's most established authorities. For that reason, the focus has been on developing regulatory expertise grounded in internationally recognised practice, particularly experience shaped by mature systems such as that of the United States. The goal is not symbolic equivalence, but alignment in scientific discipline, evidentiary scrutiny, and regulatory

judgement.

This sequencing is deliberate. External validation must precede domestic confidence. If Hong Kong can demonstrate that its professionals understand how safety, efficacy, and clinical data are evaluated at the highest level, credibility will follow more naturally, both regionally and internationally. Alignment with global regulatory norms is essential if the CMPR is to operate as a serious platform rather than a local administrative structure.

At the same time, the concern that regulatory development could become a vehicle for industrial promotion warrants a clear response. Patient safety is not secondary to economic ambition; it is the condition for any lasting credibility. When reference is made to a “Hong Kong version” of leading regulators, it reflects a commitment to standards rooted in science and patient data, not a branding exercise. Without consistent, transparent, and data-driven decision-making, no regulator can earn trust, regardless of its strategic positioning.

Hong Kong begins without a long history of primary drug evaluation, which makes the task more complex and more demanding. Infrastructure, expertise, and institutional culture must be built together. Recognition will take time, but if the foundation rests firmly on safety and scientific integrity, global acceptance becomes possible. Without that discipline, any aspiration to serve as a bridge between markets would remain rhetorical rather than real.

How does manufacturing fit within Hong Kong’s broader regulatory and innovation strategy, given the city’s limited production capacity and medicines that may be reviewed will probably manufacture on other jurisdictions …

Manufacturing is an integral component of regulatory credibility, particularly in areas such as quality control and plant inspection, but it must be considered within the context of Hong Kong’s structural position. The city does not have the industrial scale of neighbouring mainland hubs, nor would it be sensible to attempt to recreate that capacity artificially. The near-term priority is therefore to strengthen research and development activity in Hong Kong, while manufacturing continues to reside largely within the Greater Bay Area, where infrastructure and industrial depth are already established. This reflects economic logic rather than institutional limitation.

That said, a regulator cannot rely solely on reviewing clinical dossiers. Competence in assessing manufacturing standards and inspection systems is essential if international trust is to be earned. The objective is not to relocate factories to Hong Kong, but to ensure that the regulatory

framework develops the technical capability to evaluate production quality against globally accepted benchmarks. Regional coordination allows this to be done without distorting the city's economic profile, while expertise and oversight capacity are built gradually and deliberately.

In parallel, Hong Kong's innovation strategy increasingly integrates life sciences with artificial intelligence, robotics, and capital markets, positioning the city as a service and coordination hub rather than a volume manufacturer. The ambition is to combine regulatory authority, research capability, and financial infrastructure into a coherent platform that attracts regional and international engagement. Limited, specialised manufacturing may emerge over time, particularly in advanced areas, but the principal objective remains the same: to establish a regulator whose standards, including its ability to oversee manufacturing, command confidence well beyond Hong Kong itself.

How do clinical trials, capital flows, and China's long-term planning framework shape Hong Kong's role within the Greater Bay Area life sciences ecosystem?

Hong Kong's ability to attract meaningful clinical trial activity cannot be separated from the structural advantages enjoyed by mainland hubs such as Suzhou and Shanghai. These cities offer deep biotech ecosystems, established industrial clusters, and strong local incentives that make it commercially rational for companies to retain both R&D and trial execution within their existing bases. From a purely business perspective, relocation only occurs when there is clear added value. Nominal offices without substantive research capability do not alter that equation, and Hong Kong must therefore offer more than symbolic presence if it wishes to compete for sustained trial activity.

The Greater Bay Area should be viewed in the context of China's long-term planning model rather than as a conventional regional initiative. Innovation and advanced technology have been embedded within successive Five-Year Plans, and regions designated as strategic platforms are expected to align accordingly. When Beijing sets a direction, alignment across ministries, municipalities, and major enterprises follows as a matter of policy logic. Commercial incentives may not be immediately evident, but political alignment often precedes market consolidation. Over time, this creates structural momentum that can reshape regional ecosystems, even when short-term signals appear weak.

That dynamic, however, does not remove the primacy of economic viability. Companies remain accountable to investors and markets, and they require tangible incentives to commit capital and

talent. For Hong Kong, the argument rests on building an integrated platform that combines regulatory credibility, academic capacity through the new medical school, and access to international capital markets. Together, these elements can create a differentiated proposition, rather than competing directly with mainland cities on manufacturing scale or trial volume alone.

The same tension is visible in the international licensing patterns of Chinese biotech companies. Many firms have chosen to out-license ex-China rights early to multinational pharmaceutical companies because sustainable profitability still depends heavily on US and European markets. China's domestic reimbursement system remains price-sensitive, limiting the commercial uptake of high-cost innovative therapies. While early licensing generates immediate capital, it risks ceding long-term global positioning. Addressing that imbalance requires stronger domestic reimbursement mechanisms and enhanced regulatory credibility, so companies are not compelled to sell their international prospects prematurely.

Viewed over a decade rather than a quarter, the trajectory is unmistakable. China's regulatory architecture has matured, its industry has professionalised, and innovation has accelerated at a pace that few anticipated twenty years ago. Hong Kong's challenge is to position itself within that long arc of structural change, recognising that durable transformation often unfolds gradually, even if its effects appear sudden in hindsight.

What developments are likely to shape the next phase of life sciences in the region, and what perspective would you offer to global industry leaders watching this evolution?

The defining characteristic of the next phase will be pace. Across pharmaceuticals, medical devices, diagnostics, and artificial intelligence, China is advancing at a speed that reshapes expectations around innovation, particularly in areas such as precision medicine and data-driven diagnostics. Hong Kong, by comparison, does not yet have the critical mass to lead in a specific technological vertical, and that reality needs to be acknowledged clearly. The implication is not that Hong Kong has missed the opportunity, but that its role is different. Scale-driven innovation will largely be set elsewhere, while Hong Kong's contribution lies in enabling structures that support how innovation is validated, financed, and ultimately brought to global markets.

For global industry, the more important message is to understand how change unfolds in this part of the world. Structural shifts rarely arrive through a single policy announcement or formal designation. They emerge through sustained agenda-setting, practical proposals, and the gradual alignment of institutions once momentum becomes impossible to ignore. I do not hold a formal

government role, nor do I need one. My approach has always been to work from the outside, to frame the argument, and to build enough pressure through industry and society for the system to move. The outcomes of that process are already visible. They may not carry individual signatures, but they signal a direction of travel that global stakeholders should take seriously.

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