

Pharma – 2012 : Pharmaceutical assets: Regulatory strategies -Shivanand P. Puthli - Panacea Biotec Ltd.

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Drug delivery systems with novel characteristics and patentable features have been developed for molecules nearing patent expiry. The primary objectives are to have enhanced therapy management and provide competitive edge in marketplace. Patented platform technologies have given rise to multiple product ranges for different molecules. Product repositioning strategy is an integral part of R&D and business development with efforts directed in sustaining the drug's market value. Advanced drug delivery systems not only bolster the commercial value but it also serves as a tool to improve the pharmacoeconomics by increasing the safety, efficacy, compliance, reducing the side effects and superior patient convenience. One of the paramount concerns is to navigate through the regulatory necessities. Specific supplementary studies may be required to prove the safety and efficacy of the newly developed pharmaceutical system depending on the quality target product profile. The regulatory pathway with regards to the product being developed should be an integral part of the product development plan and should be appraised at the commencement of product development activity.

Age-related conditions are the leading causes of death and health-care costs. Reducing the speed of aging would have enormous medical and financial benefits. Myriad genes and pathways are known to manage aging in model organisms, fostering a replacement crop of anti-aging companies. Approaches range from drug discovery efforts to big-data methods and direct-to-consumer (DTC) strategies. Challenges and pitfalls of commercialization include reliance on findings from short-lived model organisms, poor biological understanding of aging, and hurdles in performing clinical trials for aging. An outsized number of potential aging-associated interventions and targets exist, but given the long validation times only a little fraction are often explored for clinical applications. If even one company succeeds, however, the impact are going to be huge. It's increasingly being recognized that directly targeting the aging process, as against individual aging-related diseases or symptoms, may be a viable strategy. This is often resulting in R&D with the last word aim of commercializing therapies directed at slowing aging itself.

Some therapeutic approaches – direct-to-consumer nutraceuticals and trial-tested scientific diets – don't require FDA approval, which may significantly reduce their time to plug. To slow the aging process, nonstandard therapies like blood-based therapies also are being tried. Big-data approaches are being harnessed in an effort to create models of healthy aging. Approaches are increasingly coming directly from aging leads to model organisms. The dream of avoiding adulthood is as old as human civilization. Given the worldwide aging of the population, developing interventions that preserve health in adulthood and postpone the onset of age-related diseases is more important

than ever. Additionally, we now know that it's possible to retard aging in animal models. Various genetic, dietary, and pharmacological interventions are shown to extend lifespan, in some cases dramatically (tenfold is that the current record), in short-lived model organisms like yeast, worms, flies, killifish, mice, and rats. Importantly, life-extending interventions not only increase longevity but can retard the onset of age-related diseases, leading to the extension of healthspan (i.e., the length of your time one lives in good health). These breakthroughs within the biology of aging and its impact on health and disease, mentioned by some as 'geroscience', have led to the promise that we'll be ready to delay or slow human aging, leading to unprecedented health benefits. Leading causes of death worldwide, and notably in industrialized countries, are age-related diseases like cardiovascular diseases, cancer, and neurodegenerative diseases. Due to the strong relationship between the aging process and age-related diseases, the advantages emerging from anti-aging science have enormous potential. employing a model of future health and spending within the USA, the effect of delayed aging leading to 2.2 years additional anticipation would yield US\$7 trillion in savings over 50 years; whereas addressing single pathologies like cancer and heart condition would yield less, mostly thanks to competing risks. Aging are often defined as a progressive deterioration of physiological function amid a rise in vulnerability and mortality with age. Here, anti-aging based therapies are defined as people who delay the onset of multiple pathologies via core biological processes related to age-related functional decline. While some therapies could also be branded as single pathology for funding, business, or regulatory reasons, we include them nonetheless if they aim aging-related processes or longevity-determining pathways and genes. Given its huge potential financial benefits, anti-aging science has tremendous commercial opportunities. The anti-aging industry has struggled within the past in terms of reputation, but driven by newer scientific breakthroughs it's been growing substantially with several young companies supported by world-leading brands like Google. Here we first review companies and approaches in anti-aging biotech. We then discuss a number of the challenges and pitfalls in business development supported anti-aging science and lastly provide a vision for a way the sector may progress within the future. The multitude of genes, processes, and pathways modulating aging in short-lived model organisms provide a plethora of potential targets for drug discovery. Many genes modulating aging and/or longevity are identified in model organisms, most of which may be grouped into common pathways and processes like insulin/insulin-like signaling, autophagy, organic process, and TOR signaling. There's also evidence that life-extending pathways tend to be evolutionarily conserved. As an example, disruption of the insulin-IGF1 pathway has been shown to increase lifespan in yeast, worms, flies, and mice and IGF1R mutations

are related to human longevity. Thus, evolutionarily conserved life-extending genes and pathways are important targets for drug discovery. Antioxidants are historically a serious focus of the sector. However, currently the thought that antioxidant pathways play a serious role in aging is being challenged, and epidemiological studies have largely did not support the supposed benefits of antioxidants. While many dietary supplements still specialise in antioxidants, few companies within the field maintain such attention. One exception is Antoxis, founded in 2005, which designs and synthesizes therapeutic antioxidants.

Biography

He earned his Ph.D. from University of Mumbai (India) and Post-doctorate from Kyoto Pharmaceutical University (Japan). He has published and presented several original research papers, articles and abstracts in peer reviewed journals and conferences. He has conceptualized innovative drug delivery platform technologies and is an inventor in number of patents. He is an invited speaker at international scientific meetings and conferences. He serves as reviewer for more than 30 scientific international journals and is on Editorial/Advisory board of various journals.

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