



MLC SERVICES - 10

MLC Quality Consultation Services

Gap-analysis support to compare current performance with a clearly defined target state.



WHAT WE COVER

Current-state review — Understand existing processes, performance and available information.

Target & gap analysis — Define the desired outcome and compare it with present arrangements.

Improvement planning — Organize the findings into priorities and an action plan.

Gap Analysis What Is a Gap Analysis?

A gap analysis is the process that companies use to compare their current performance with their desired, expected performance. This analysis is used to determine whether a company is meeting expectations and using its resources effectively.

A gap analysis is the means by which a company can recognize its current state—by measuring time, money, and labor—and compare it with its target state. By defining and analyzing these gaps, the management team can create an action plan to move the organization forward and fill in the performance gaps.

KEY TAKE AWAYS:

Through gap analysis, an organization examines its current performance vs. its target performance. A gap analysis can be useful when companies aren't using their resources, capital, or technology to their full potential. By defining the gap, a firm's management team can create a plan of action to move the organization forward and fill in the performance gaps. There are four steps to a gap analysis: defining organizational goals, benchmarking the current state, analyzing the gap data, and compiling a gap report. Gap analysis can also be used to assess the difference between rate-sensitive assets and liabilities.

Understanding Gap Analysis



When organizations aren't making the best use of their resources, capital, and technology, they may not be able to reach their full potential. This is where a gap analysis can help.

A gap analysis, which is also referred to as a needs analysis, is important for any type of organizational performance. It allows companies to determine where they are today and where they want to be in the future. Companies can reexamine their goals through a gap analysis to figure out whether they are on the right track to accomplishing them.

Gap analyses were widely used in the 1980s, typically in tandem with duration analyses. A gap analysis is considered harder to use and less widely implemented than a duration analysis, but it can still be used to assess exposure to a variety of term structure movements.

There are four steps in a gap analysis, ending in a compilation report that identifies areas of improvement and outlines an action plan to achieve increased company performance.

The "gap" in a gap analysis is the space between where an organization is and where it wants to be in the future.

How to Conduct a Gap Analysis

Some gap analysis models break the following steps into four processes. Others are a little more elaborate and expand the analysis into a few additional steps. In either case, a gap analysis entails understanding your current position, determining where you want to end up, and devising a plan on how to arrive at the desired endpoint.

Step 1: Identify Your Current State

A gap analysis starts by focusing on where your organization is currently operating at. This includes researching the products it offers, customers it serves, geographical locations it reaches, and benefits it offers to its employees. This information can be quantitative (i.e., financial records as part of required filings) or qualitative (i.e., surveys or feedback from key stakeholders).

Often, a company will perform a gap analysis because it is already aware of an issue. For example, customer feedback surveys have generated poor results, and a company wants to investigate why and implement remedies. Before it can dream of what it wants to become, it must understand why these errors are happening, when issues are arising, and who the change management leaders must be.

Step 2: Identify Your Future State

The crux of gap analysis resides in this step, where a company must identify what it wants to become. This stage must be done with great care, as the identity that a company wants to have will dictate the strategic steps that it must make to obtain those goals.

In gap analysis, a company must make specific, measurable goals to yield the greatest long-term success. For example, in the situation above, it would do the company little good to set the goal of "becoming better at customer service." Instead, the company must identify more trackable metrics, such as "achieve customer satisfaction of 90% within 12 months."

Another way of identifying the desired outcome is to analyze what competitors or other market participants are doing. It may be easier to identify when another company is doing something well and attempt to emulate that.



Step 3: Identify the Gaps

With the current state and future state defined, it's time to bridge the two and understand where the most critical differences lie. In our running example, it's in this stage that a company realizes it may be woefully understaffed, has not provided enough staff training, or does not have the technical capability to keep up with customer inquiries.

Step 4: Evaluate Solutions

Now that a company has defined its deficiencies, it's time to come up with plans on how it will reach its target state. Sometimes, there may only be one solution; other times, the gap analysis may call for several simultaneous changes that must work in tandem.

To gauge whether a solution will work, it must often be quantifiable with ways to measure change. Our example of improving customer service may have an easy metric, such as customer satisfaction percentage. Other gap analysis findings such as deficiencies in brand recognition may require more creative, thoughtful solutions that can still be evaluated.

Step 5: Implement Change

Once risk control has been implemented, establish a system for monitoring its effectiveness. Quality risk management should be continuously reviewed, especially when:

This implementation stage often entails following a detailed set of processes at a specific cadence. As part of the gap analysis, the company has a defined outcome, and careful steps must be taken to ensure that more damage isn't caused instead of cured. For example, consider employees feeling overwhelmed and discouraged from laborious training. An effort of making workers more proficient may lead to loss of productivity or decreased morale.

Step 6: Monitor Changes

For this reason, the company must also conclude its gap analysis by monitoring any changes. Sometimes, the company took exactly the right steps. Other times, the gap might have been wider than the company thought or the company failed to adequately assess its current position. In any case, gap analysis can be a circular process where after changes have been made, the company can reevaluate its current position and where it compares against regarding other future states.

A gap analysis often contains sensitive information; therefore, companies will often not disclose their gap analysis model. In addition, the analysis would tip off competitors about the direction of the company.

Types of Gap Analysis

Market Gap Analysis

Also called product gap analysis, market gap analysis entails making considerations about the market and how customer needs may be going unmet. If a company is able to identify areas where product supply is not meeting consumer demand, then the company can take measures to personally fill that market gap. This type of analysis may be performed by external consultants who have more expertise in these areas of business in which the company may not currently be operating.



Strategic Gap Analysis

Also called performance gap analysis, strategic gap analysis is a more formal internal review of how a company is performing. The analysis often entails comparing how a company has done against long-term benchmarks such as a five-year plan or a strategic plan.

A strategic gap analysis may also be performed to compare how a company is faring against its competitors. This type of analysis may unearth ways that other companies are utilizing personnel or capital in more strategic, resourceful ways. This type of information may be hard to come by, especially if departed employees have signed nondisclosure agreements and the company does not publicly disclose much information about processes.

Financial/Profit Gap Analysis

A company may choose to directly analyze where its company may be falling short compared to competitors by looking specifically at financial metrics. This may include pricing comparisons, margin percentages, overhead costs, revenue per labor, or fixed vs. variable components. The ultimate goal of a profit gap analysis is to determine areas in which a competitor is being more financially efficient. This information can then be used in further, broader gap analysis types.

Skill Gap Analysis

Instead of looking at the financial aspects of a company, a business may choose to look at the human element instead. A skill gap analysis helps determine if there is a shortfall in knowledge and expertise with current personnel. A skill gap analysis must clearly define the goals of the company, then map how current laborers may fit into that design. A skill gap analysis may lead to the recommendation of simply training existing staff to incur new skills or seeking outside expertise to bring in new personnel.

This type of analysis is especially important for innovative companies that must rely on having direct skill sets to continue to be competitors (or leaders) in their industry. In addition, skill gap analysis is critical for small companies that must rely on a smaller staff to operate. In this case, individuals must often have diverse, flexible talents that can be useful in many different aspects of the business.

Compliance Gap Analysis

Often leveraging internal audit functions, a compliance gap analysis evaluates how a company is faring against a set of external regulations that dictate how something should be getting done. For example, a company may internally evaluate its accounting and reporting functions in advance of seeking an external auditor to provide an opinion on its financial statements.

Compliance gap analysis tends to be preventative and defensive as opposed to more strategic forms of gap analysis. For example, instead of performing a gap analysis to attempt to gain a greater percentage of market share, compliance gap analysis often has the intention of meeting regulations, avoiding fines, meeting reporting requirements, and ensuring that external deadlines can be met successfully.

Product Development Gap Analysis

As a company builds new products, gap analysis can also be performed to analyze which functions of the products will meet market demand and where the product will fall short. This type of gap



analysis is often associated with the development of software products or items that take a long time to develop (in which the market demand may have shifted).

During product development gap analysis, a company may also evaluate which aspects of the product or service have been successfully implemented, delayed, intentionally eliminated, or still in progress. With a blend of multiple types of gap analysis above, the company can then perpetually evaluate how its product plan is changing and whether it has the internal resources to meet the internal gaps needed for product development completion.

Gap Analysis Tools

To assist with the gap analysis process, companies have an assortment of tools at their disposal. The tools listed below have an intended use that is best suited for a specific aspect of a gap analysis.

SWOT Analysis

One of the more recognizable analysis tools, SWOT analysis determines a company's strengths, weaknesses, opportunities, and threats. As a gap analysis tool, a company can evaluate both internal and external factors that it can improve upon or realize its lead on.

In a SWOT analysis, a company evaluates its strengths and weaknesses as part of internal analysis. During a gap analysis, a company may choose to divert resources from its strengths, especially if it feels comfortable with its current market lead. On the other hand, companies may be more interested in what its weaknesses are and how far behind it may be from outside parties. In some cases, companies may decide that its weaknesses cannot be overcome due to barriers of entry, massive capital investment requirements, or consumer preferences.

The other half of a SWOT analysis relates to external forces often outside of the control of a company. The opportunities and threats that a company faces are often the uncontrollable forces that pose risk of the findings of a gap analysis not materializing. For example, a company may outline the plan to capture greater market share by releasing a new product. Should the threat of a government tariff on the product increase the per-unit cost, the company's gap may be more difficult to close.

Fishbone Diagram

A fishbone diagram, also called a cause-and-effect diagram or an Ishikawa diagram, is useful to identify what might be causing problems. It is also helpful to encourage creative thinking when sleuthing through a business constraint.

A fishbone diagram is created by determining the problem at hand and writing that at the center of an area. Then, major categories are written on branches that expand away from the main problem. Eventually, additional branches are added to these branches that identify why problems within each category exist. In the end, the fishbone diagram attempts to break a large, complex problem into various aspects that can be more easily approached and solved.

McKinsey 7S

The McKinsey 7S framework identifies seven elements that are key to determining how well a company performs and what has an impact on how it operates. The model contains three "hard elements" of strategy, structure, and systems, along with four "soft elements" of shared values, skills, style, and staff.



Using the McKinsey 7S model, a company can identify how each area fits into prevailing gaps and how the company can influence each aspect to better conform to long-term objectives. As adjustments are made, it's often recommended to iteratively monitor and review company performance.

Nadler-Tushman Model

The Nadler-Tushman model is used specifically to identify problems, understand how a company may be underperforming, and determine how to address that performance. The core of the Nadler-Tushman model is based around the concept that aspects within a company should be aligned and work together; otherwise, the company will not be as successful.

The model is centered around different components, including culture, work, structure, and people. These four core principles receive data that is input (a company's strategy) as well as output (a company's performance). The end goal is to determine how each of the four components are working together.

PEST Analysis

A PEST analysis entails gauging external factors and how they may impact the profitability of a company. PEST stands for political, economic, social, and technological. A common variation of PEST analysis is PESTLE analysis, which also incorporates legal and environmental concerns.

PEST analysis can help with a gap analysis, as a company may not be considering external factors that may cause, exacerbate, or solve current gaps. For example, government legislation may cause a company's product to become much more expensive to export. In this case, a company may have a potential gap should external forces shift in a way that adversely impacts the company.

Companies often use a combination of these tools, as findings from one tool may contribute to the analysis in another.

When to Use a Gap Analysis ?

Companies should perpetually evaluate the products it offers, the customers it serves, the market need it fills, and the efficiency of its operations. However, there may be certain times when a more formal gap analysis is warranted. These times include:

During project management. As a company moves from the starting phase to the ending phase of a project, it may continually evaluate that the project has sufficient resources, knowledge, talent, and information to be completed successfully. Because some products with multiyear development cycles face risk of changing external situations, companies are well-suited to perform gap analysis during a long-term project. Planning for strategic endeavors. Whether forming long-term budgets, contemplating corporate restructurings, or lining up a potential acquisition, gap analysis is informative when attempting to make strategic decisions. This ensures that proper resources are allocated to the right areas to ensure long-term success. For example, expansion into a new geographical area may pose political risk, geographical risk, currency risk, and culture risk. A company should perform gap analysis to understand how severe these risks are and what additional resources (if any) are needed to handle each area. Wanting to understand performance deficiencies. In addition to strategic benefits, gap analysis can unearth areas of operations where shorter-term, day-to-day functions can improve. Although this type of use is more reactionary, companies can choose to preemptively attempt to better understand areas of operation. For example, a specific cost



center may come in substantially over budget; the company may simply want to better understand what happened and what steps need to be taken to become more successful. Marketing to external parties. Though gap analysis holds most benefit to internal parties, it may also be used to communicate plans to external investors. For example, private companies can identify where its shortfalls occur. After forging an internal plan, this plan can then be revealed to outside parties as part of a capital investment request or seed funding round. By being open, transparent, and strategic about its shortfalls, a company may find outside parties more willing to partner and invest in its growth. Benefits of Gap Analysis

Because gap analysis can be used in an assortment of ways, it carries with it a wide variety of benefits. Each benefit listed below may pertain to only one specific type of gap analysis. Still, companies performing gap analysis may experience:

Improved profitability. Companies that assess gaps and preemptively determine shortfalls can be better prepared to incur spending at optimal times, have resources on hand (instead of having to pay extra capital to secure later), and run more efficiently. Better manufacturing processes. Realizing and preventing gaps from building in the manufacturing process leads to stronger production, more efficient delivery logistics, raw materials being on-site at the correct location when they are needed, and the avoidance of bottlenecks due to any shortfall along the process. Increased market share. By combining the first two benefits, a company can have an improved presence in the market by having increased sales, revenue dollars, customers, and market share. Happier employees and customers. Instead of being reactionary to employee or customer needs, companies that perform gap analysis can address these potential issues before they strain relationships or cause individuals to turn to competitors. Operational efficiency. By better understanding where it may not be operating well, a company can make changes to improve day-to-day functions. Decreased risk for long-term endeavors. By identifying the resources needed and potential shortfalls, companies can plan for gaps and identify problems before they occur. Gap Analysis in Finance/Asset Management

Gap analysis is also a method of asset liability management that can be used to assess interest rate risk (IRR) or liquidity risk, excluding credit risk. It is a simple IRR measurement method that conveys the difference between rate-sensitive assets and rate-sensitive liabilities over a given period of time. This type of analysis works well if assets and liabilities are composed of fixed cash flows. Because of this, a significant shortcoming of gap analysis is that it cannot handle options, as options have uncertain cash flows.

Consider a situation where a company wants to make an investment but wants to ensure that it has enough capital on hand to cover contingent situations. The company can review cash flows, determine risks, and assess where potential cash flow shortfalls may occur. This is especially prevalent in long-term projects, high-risk projects, or projects sensitive to macroeconomic or external forces.

Example of Gap Analysis:

For years, GameStop Corp. held its place in the market as a competitor in the video gaming industry. Customers could enter a physical location to either trade in video games from their existing collection or buy games, consoles, or gaming merchandise.

There is little public disclosure regarding the analysis or strategy performed by company management. However, in July 2022, the company released its non-fungible token (NFT) marketplace, allowing gamers, creators, collectors, and community members to buy and sell NFTs. Though this business endeavor was launched primarily relating to artwork, the marketplace is



expected to expand into gaming endeavors with a variety of NFT usages.

To have made this business decision, GameStop could have performed a gap analysis. It could have:

Analyzed its current position in the market. Realizing how digital transformation has reshaped many industries, it may have realized that its existing business model of in-store business may not be sustainable (although the company also has a website to buy goods). Analyzed where it would like to be. The company may have determined that it wanted to maintain its presence as industry leader in the video game distribution industry. This likely would have resulted in the company realizing that the shift to digital gaming, including the rise of NFTs in a gaming context, could be the next potential market disruptor. Determined a plan to get from today to the future. This would have entailed the release of the NFT marketplace in addition to other, potentially not yet disclosed strategic endeavors. Execution of the plan. In addition to releasing the NFT marketplace, GameStop announced relationships with several Ethereum Layer 2-based entities in addition to bringing on a variety of staff with experience relating to digital assets and blockchain.

Though the ultimate internal discussions around the NFT marketplace are not known, one can infer that GameStop performed a gap analysis to understand that its existing position as a brick-and-mortar store could be enhanced with a new, digital marketplace.

Why is a gap analysis performed?

A gap analysis is performed to understand where a company may be lagging against its goals or objectives. It's a form of analysis that evaluates what it will take for a company to get from its current position to its future dream state.

What are the types of gap analysis?

Gap analysis can be performed in an assortment of business situations. Most often more strategic in nature, gap analysis can be performed to better understand market positioning, product success, labor needs, or long-term financial positioning. Gap analysis can also be used to analyze more operational aspects such as short-term budget deficiencies or current employee satisfaction.

What are the fundamental components of a gap analysis?

Gap analysis must always start with an analysis of a company's current position. Without understanding where it currently is, a company can't adequately make a plan to get to where it wants to go. In addition to identifying where it is today and where it wants to be in the future, gap analysis entails crafting a plan with implementation steps that can be tracked and measured to hold change managers accountable.

How do gap analysis and SWOT analysis differ?

SWOT analysis is a tool that is often used as part of gap analysis. As part of SWOT analysis, a company identifies its strengths and weaknesses. Then, the company should understand whether those strengths and weaknesses are suitable to where the company wants to be. Gap analysis is the plan that attempts to change a company's strengths and weaknesses. In addition, the opportunities and threats identified as part of a SWOT analysis are the risks that the plan outlined as part of a gap analysis will not be successfully carried out.

What is static vs. dynamic gap analysis?



These two terms often refer to analyzing the performance and risks associated with banks or financial firms. Static gap analysis looks at the firm's sensitivity to changes in interest rates. Dynamic gap analysis looks at the firm's discrepancy between its assets and liabilities.

The Bottom Line

A gap analysis is a technique that companies can use to evaluate their current position, decide their dream position, and formulate a plan on how to bridge the gap. A company may choose to perform a gap analysis if it is struggling operationally or if it simply wants to become more strategic. In either case, there are several tools, such as SWOT analysis, PEST(LE) analysis, or a fishbone diagram, that can help the company formulate and execute a long-term plan.

What is Quality Risk Management?

Quality risk management is a systematic, risk-based approach to quality management. The process is composed of the assessment, control, communication, and review of quality risks. It is especially critical in the pharmaceutical industry, where product quality can greatly affect consumer health and safety.

Quality Risk Management Principles

According to the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), quality risk management has two primary principles, which are:

Quality risk evaluation should be based on scientific knowledge, such as data and research, and ultimately work towards the protection of consumers. The higher the risk level, the stronger a QRM process should be. The level of effort, formality, and documentation should be equal to the risk level.

These principles can be seen in the examples provided below by the European Commission in its Good Distribution Practice (GDP) Guidelines for Medicinal Products:

Temperature and environment control: Temperature mapping should be repeated according to the results of a risk assessment. Equipment: Equipment should be calibrated at defined intervals based on a risk and reliability assessment. Qualification and Validation: The scope and extent of key equipment qualification and/or key process validation must be determined using a documented risk assessment approach. Operation – Principles: All means available must be used to minimize the risk of falsified medicinal products entering the supply chain. Returned Medicinal Products: Returned products must be handled according to a documented, risk-based process. Transportation: Risk assessment of delivery routes should be used to determine where temperature controls are required. Why Quality Risk Management is Important?

Quality risk management is important because it can facilitate better and more informed decisions. With QRM, decision-making has the following qualities:

Decisions are data-driven instead of subjective. The potential impact on the lives of consumers is prioritized.

Another benefit is that companies can use risk level as the basis for prioritization, leading to a more efficient use of resources. Moreover, it helps build a culture of trust and transparency among companies and regulatory authorities.



Quality risk management is also a requirement of GDP, an internationally recognized set of standards for ensuring the quality of medicines throughout the supply chain. While GDP is primarily enforced in Europe, there has been an increase in its use in the United States and other countries.

Quality Risk Management Process

Step 1: Before Starting

Form a cross-functional team and choose a leader. Example QRM team:

Quality manager – Leader

- Business developer
- Lead engineer
- Operations manager
- Sales and marketing head
- Senior data analyst
- Corporate lawyer
- Clinical expert
- Manufacturing director

Each member of this team will be responsible for coordinating quality risk management across various functions and departments in the company.

Step 2: Risk Assessment

Define the problem: Ask “What might go wrong?” Risk identification: Identify hazards related to the problem. Risk analysis: Estimate risk associated with identified hazards. For each estimated risk, define the likelihood of occurrence and the severity of consequences. Risk evaluation: Based on risk analysis, evaluate each risk using a 3×3 risk matrix, 4×4 risk matrix, or 5×5 risk matrix based on your needs.

To quantify the expression of risk, assign a numeric value to each likelihood and severity category. The formula for calculating the risk level based on these values is up to you.

Set rules for defining the overall risk level: For example, if more than half of the risks are high, then the overall risk level is high.

The output of the risk assessment will either be a numeric value or qualitative description expressing the overall level of risk posed by the problem.

Step 3: Risk Control Selection

The key focus of this step is choosing between risk reduction and risk acceptance. Answer and discuss the guide questions below with other QRM team members before making a decision:

- Is the risk above an acceptable level?
- What can be done to reduce or eliminate the risk?



- What is the appropriate balance among benefits, risks, and resources?
- Are new risks introduced as a result of initial risk being controlled?

Also keep in mind that the amount of effort used for risk control should be equal to the significance of the risk/s. If needed, refer to the output of the risk assessment in Step 2 or conduct a cost-benefit analysis to help determine the appropriate risk control.

Step 4: Risk Control Implementation

Risk reduction is the set of actions taken to minimize the likelihood of occurrence and the severity of consequences. It may also include improving the detectability of hazards (i.e. making hazard identification easier) and risks (i.e. catching risks before they cause further damage). Risk acceptance is a decision to accept risk since it cannot be eliminated. This form of risk control is typically only chosen when mitigating the risk is out of the QRM team's control. Another case where it may be the best option is when risk reduction has already been applied and the remaining risk is at an acceptable level.

Step 5: Risk Review & Risk Communication

Once risk control has been implemented, establish a system for monitoring its effectiveness. Quality risk management should be continuously reviewed, especially when:

there is new research, experience, knowledge, or data on specific risks

- there are events that may have an impact on the original decision/s and
- factors influencing the overall risk level have changed.

Meanwhile, risk communication involves sharing information on the entire process with stakeholders who are not part of the QRM team. It also includes documenting the QRM team's thought process at each step and the results they were able to achieve after completing a step.

Quality Risk Management Tools

While following the steps of the quality risk management process above is sufficient for starting with QRM, certain industries or companies may need the help of recognized tools to fully deploy their strategy. Below are 3 quality risk management tools, their descriptions, and templates to help get you started:

FMEA

Failure Mode Effects Analysis (FMEA) is a systematic method of anticipating potential failures in a process, product, or design and mitigating the negative impact of those failures on consumers. Key elements of this tool are mechanism of failure, risk priority number (RPN), and follow-up corrective actions.

HACCP

Hazard Analysis Critical Control Points (HACCP) is a monitoring system for identifying and controlling hazards. First, a hazard analysis is performed on each step in the production process. If there is an opportunity to prevent, mitigate, or eliminate a hazard, the step is considered a critical control point.



HAZOP

Hazard Operability Analysis (HAZOP) is a risk management technique used to determine functional flaws in manufacturing systems. Similar to FMEA, it involves exploring different scenarios where a process, design, or procedure could deviate from its intended function.

Effectively Manage Quality Risks Through QRM Training

One thing you can control is the way you address and mitigate risks involved in quality management. Hence, you must standardize these processes in your organization by providing regular QRM training to employees. With the help of MLConsultants Training, leaders, supervisors, and facilitators can create and deploy training programs targeted to the needs of the business. They can also monitor course completion progress and make necessary follow-ups to ensure no one misses training requirements for compliance. Through easy-to-grasp training courses and modules created using the platform, employees can take charge of their knowledge and skill development to help manage quality risks and minimize their negative impact on the organization.

Why use MLConsultants?

Streamline decision-making with data-driven insights, efficiently manage quality risks, and reduce their impact on the organization using a digital platform solution like MLC

Simplify processes with digital checklists

- Receive professional reports and share instantly
- Use for teams of any size

Streamline your organization's operations and workflow with our digital checklist. It empowers you to:

Maintain safety and compliance standards with customizable templates

- Increase your team's engagement and accountability including contractors and stakeholders
- Create powerful workflows by integrating your existing software
- Gain greater visibility and transparency with real-time reporting
- Access unlimited storage and data security for your reports

Take advantage of our comprehensive features to optimize your operations and enhance workplace safety today.

Useful details to share when you enquire

- Current performance and process information
- Target outcomes and business priorities
- Available resources and improvement constraints



TALK TO MLC

+91 77269 32023 · +91 99498 45759 | info@mlcqehs.com

H. No. 06-096/7/5, Manikya Nagar, Chintal, Quthbullapur, Medchal (Malkajgiri), Hyderabad, Telangana – 500054, India

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